Award Number: W81XWH-15-C-0070

TITLE: Enhancing mHealth Technology in the PCMH Environment to Activate Chronic Care Patients

PRINCIPAL INVESTIGATOR: Ronald W. Gimbel,

CONTRACTING ORGANIZATION: Clemson University
Clemson, SC 29634

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Clemson, SC 29634

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14. ABSTRACT - The potential of mobile health (mHealth) technologies in the care of patients with diabetes and other chronic conditions has captured the attention of clinicians and researchers. Efforts to date have incorporated a variety of tools and techniques including web-based portals, tailored behavioral text messaging, remote collection of biometric data, electronic coaching, electronic-based health education, secure e-mail communication between visits, and electronic collection of lifestyle and quality of life surveys. Each of these tools, used alone or in combination, have demonstrated varying degrees of effectiveness. Some of the more promising results have been demonstrated using regular collection of biometric devices, tailored behavioral messaging, secure e-mail communication with clinical teams, and regular reporting of quality of life variables. In this study, we seek to incorporate several of the most promising mHealth capabilities in a patient centered medical home (PCMH) workflow. We aim to address underlying technology need and gaps related to the use of mHealth technology and the activation of patients living with Type-2 diabetes. Stated differently, we enable supporting technologies while seeking to influence patient activation and self-care activities.

15. SUBJECT TERMS

MHCE, Mobile Health Care Environment

mHealth, mobile health

MHS, Military Health System

PAM®, Patient Activation Measure

CS-PAM®, Clinician Support for Patient Activation Measure

PCMH, patient centered medical home

SDSCA, Summary of Diabetes Self-Care Activities

SUS, System Usability Scale

Type 2 Diabetes

User-Centered Design Research

TATRC, Telemedicine and Advanced Technology Research Center

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1. **INTRODUCTION:**

The potential of mobile health (mHealth) technologies in the care of patients with diabetes and other chronic conditions has captured the attention of clinicians and researchers. Efforts to date have incorporated a variety of tools and techniques including web-based portals, tailored behavioral text messaging, remote collection of biometric data, electronic coaching, electronic-based health education, secure e-mail communication between visits, and electronic collection of lifestyle and quality of life surveys. Each of these tools, used alone or in combination, have demonstrated varying degrees of effectiveness. Some of the more promising results have been demonstrated using regular collection of biometric devices, tailored behavioral messaging, secure e-mail communication with clinical teams, and regular reporting of quality of life variables. In this study, we seek to incorporate several of the most promising mHealth capabilities in a patient centered medical home (PCMH) workflow. We aim to address underlying technology need and gaps related to the use of mHealth technology and the activation of patients living with Type-2 diabetes. Stated differently, we enable supporting technologies while seeking to influence patient activation and self-care activities.

2. **KEYWORDS:**

MHCE, Mobile Health Care Environment
mHealth, mobile health
MHS, Military Health System
PAM®, Patient Activation Measure
CS-PAM®, Clinician Support for Patient Activation Measure
PCMH, patient centered medical home
SDSCA, Summary of Diabetes Self-Care Activities
SUS, System Usability Scale
Type 2 Diabetes
User-Centered Design Research
TATRC, Telemedicine and Advanced Technology Research Center

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

FOCUS: Phase I user-centered design research

Major Task 1: Identified potential DM patients to participate in the study **(COMPLETED 10/31/16) -** For Phase 1 of Patient recruitment, we requested use of a ***Partial HIPAA Waiver of Authorization*** **for Recruitment** for patient recruitment. Patient recruitment occurred via review of the PCMH clinic schedule, referrals from providers, distributed fliers, and population health databases. We also prescreened potential subject's medical record for inclusion and exclusion criteria to verify eligibility for the study.

Major Task 2: Recruited, randomized, and consented patients to participate in user-centered design research; n=15 per site **(COMPLETED NOV 2016) -** For Phase 1 for the patients, an Informed Consent Document (ICD) and HIPAA authorization was be sought in advance from each prospective subject and appropriately documented in accordance with 32 CFR 219.117. The senior research associate or Site PI was available to answer any questions that the patients had in regards to the study. For Phase 1 clinicians, a minimal risk information sheet was given to providers before participating in any study-related procedures. The senior research associate or Site PI was available to answer any questions that the clinician may have had in regards to the study. If the PI was the supervisor for any of the clinicians, the SRA recruited their subjects to prevent any perception of coercion or undue influence.

Phase 1, Patient-Participants: Patient recruitment occurred via review of the PCMH clinic schedule, referrals from providers, distributed fliers, and population health databases. Patients were also prescreened via their medical record for inclusion and exclusion criteria to verify eligibility for the study. The PI verified inclusion and exclusion criteria.

Phase 1, Provider-Participants: Clinicians were invited to participate by word of mouth from the site PI and the SRA. A brief background of the study was given and volunteers who were interested and wanted to support the study met with the SRAs and were asked to review the minimal risk information sheet to be included in the study.

Major Task 3: Conduct 4-5 days of user-centered design research (qualitative) with research participants – each site **(COMPLETED 12/3/16)**

- Phase I travel and research to Nellis AFB was conducted 16-19 NOV 2016. Phase I travel and research to MAMC was conducted 30 NOV – 3 DEC 2016.

Research Steps (Phase I). Provider-participants participated in focus group sessions held in a conference room or other suitable location at both sites during a one hour period with two or more of the research team regarding the use of biomedical devices and technology in patient self-management of diabetes. They were shown a series of mock up (under development) technology devices and user interfaces and asked to provide feedback on their preferences. The session was audio recorded for note-taking purposes.

Major Task 4: Analysis and reporting of user-centered design research **(COMPLETED 12/15/16)**

Subtask 1: Assembled, coded, interpreted and triangulated all data collected in user-centered design research **(COMPLETED 12/15/16)**

Subtask 2: Authored user-centered design assessment report; to be used in infrastructure/design modification prior to Phase II study ***(Report + manuscript = major milestone #1)*** **(COMPLETED 12/15/16)**

Subtask 3: Advised TATRC of user-centered research driven modification recommendations to MHCE; request implementation of recommendations prior to Phase II feasibility study **(COMPLETED 12/15/16)**

FOCUS: MHCE modification and readiness to conduct Phase II feasibility study

Major Task 1: TATRC team modified MHCE based on findings from user-centered design research **(COMPLETED 6/30/17)**

Major Task 2: Coordinated all logistical issues and other preparation for Phase II research **(COMPLETED 6/30/17)**

Major Task 3: Identify potential DM patients to participate in the study **(Ongoing During Recruiting Process)**

Major Task 4: Recruit, randomize, and consent patients to participate in feasibility study **(Recruiting Process Underwa)**

FOCUS: Phase II formal feasibility study

Major Task 1: Launch and conduct a formal 12 month feasibility study of patient activated MCHE **(Ongoing Recruitment Phase). As of 8/14/17, there are a total of 120 participants recruited at both sites with 50 patients recruited in the intervention group and 46 patients recruited in the control group.**

Major Task 2: Per protocol collect and analyze (using appropriate statistical testing) data from MHCE, clinical data from SRAs (each site), and other data sources **(Currently Ongoing – patient information from devices and surveys are populating data)**

What was accomplished under these goals?

What opportunities for training and professional development has the project provided? (Not applicable for current reporting period. Training and professional development will concur during and following Phase II)

a. **How were the results disseminated to communities of interest?**

2016 AMSUS Annual Continuing Education Meeting - Poster #1 – presented 11/29/16, National Harbor, Maryland - "New Biometric Data Collection, Analysis and Visualization in the DoD's Mobile Health Care Environment"; Authors: Ron Gimbel, PhD, Clemson University; Jeanette Little, MS, TATRC; Terry Newton, MD, OTSG – USA.

2016 AMSUS Annual Continuing Education Meeting - Poster #2 – presented 11/29/16, National Harbor, Maryland – "Enhancing mHealth Technology in the DoD's PCMH Environment to Activate Type 2 Diabetes Patients; Authors: Ron Gimbel, PhD; Joel Williams, PhD; Liwei Chen, MD, PhD; Cheryl Dye, PhD; Karen Edwards, MEd; Jeanette Little, MS, Terry Newton, MD

DoD publication clearance was obtained from USA, USAF, TATRC for our first manuscript submitted to JMIR Research Protocols for peer review DEC 2016; JMIR Research Protocols approved manuscript for submission on 12 FEB 2017; JMIR Research Protocols manuscript published on 6 MAR 2017: *Enhancing mHealth Technology in the patient centered medical home environment to activate Type 2 diabetes patients: A multi-site feasibility study protocol;* http://www.researchprotocols.org/2017/3/e38/

Poster delivered for American Academy of Health Behavior Scientific Meeting, Tucson, AZ; *Improving Diabetes Self-management through Messages Tailored to Patient Activation Levels*; delivered 19-22 MAR 2017.

Presentation approved for the Military Health System Research Symposium, Kissimmee, FL; *Mobile Health Apps in the Medical Theater of Operation – Exploring the Usability of a Mobile Application for Improving Chronic Disease Self-management in the Patient Centered Medical Home Environment.* AUG 2017.

b. **What do you plan to do during the next reporting period to accomplish the goals?**

FOCUS: MHCE modification and readiness to conduct Phase II feasibility study

Major Task 4: Recruit, randomize, and consent patients to participate in feasibility study – Recruitment process should be completed by 31OCT2017. We have requested a no-cost extension to complete the study so that our end date for Phase II, along with study wrap-up and reporting should be 31DEC2018.

FOCUS: Phase II formal feasibility study

Major Task 1: Launch and conduct a formal 12 month feasibility study of patient activated MCHE

Major Task 2: Per protocol collect and analyze (using appropriate statistical testing) data from MHCE, clinical data from SRAs (each site), and other data sources

Major Task 3: Author 2-3 manuscripts on patient activated MHCE system design, implementation and on-going use in chronic care self-management (First manuscript has been approved and published; second manuscript is under completion now; future manuscripts will be forthcoming as data is populated)

FOCUS: Phase II study wrap up and reporting

Major Task 1: Complete all data analysis from Phase II study – n/a

Major Task 2: Complete formal reporting and follow-on manuscripts (if any) from Phase II study. Formal DoD report will include specific design and investment recommendations grounded in evidence collected during Phase I and Phase II of the study – n/a

Major Task 3: Formal study closure and IRB closure reports – n/a

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?** Research benefits include improved understanding of how to advance three joint PCMH principles (coordination of care, improved quality and safety, and enhanced access to care) through the use of mobile technology. We expect to improve the understanding of how to include mHealth technology into the PCMH workflow, as well as exploring how to use mHealth technology in the activation of patients diagnosed with Type 2 diabetes. We also explore how patient complexity and degree of "sickness" may influence whether and how patients use mHealth technologies in self-management of their disease. Finally, we will map patient-entered biomedical data into clinical documentation and a decision support platform useful in chronic care management.
- **What was the impact on other disciplines?** The Clinical Advisory Team, populated by MHS clinicians, academicians, and research associates, established clinical and safety thresholds and provided clinician preferences on optimal data visualization and clinical workflow. To ensure the MHCE thresholds were grounded in evidence, CAT members compared them to those presented in current clinical practice guidelines, systematic reviews, and other peer-reviewed biomedical manuscripts.
- **What was the impact on technology transfer?** (Not applicable for this reporting period)
- **What was the impact on society beyond science and technology?** Phase II research will make an impact on society by improving patient activation through the use of the MHCE which is expected to improve their chronic disease self-management behaviors. When chronic disease self-management behaviors improve, clinical outcomes and a reduction of high-intensity health services utilization will decrease. Our efforts and expected knowledge generated from this study will make a substantial contribution on how to use PAM in health services delivery.

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change** (Nothing to report)
- **Actual or anticipated problems or delays and actions or plans to resolve them**

Due to a nine-month delayed approval from MAMC IRB (submitted NOV2016 and approved SEPT2017), Phases I and II were not scheduled as planned. Phase II research began in early July, 2017 which has required a no-cost extension for the execution of the forma 12-month study into year three.

TATRC adaptations of the MHCE platform, incorporating recommendations from Phase I research and other technical challenges, have also delayed the start date for Phase II by six months.

- **Changes that had a significant impact on expenditures**

The delay in Phase I and Phase II research activities (and resulting expenditures) have had a significant impact on expenditures, although the study should be completed with the same contract budget as originally set for the contract period. Total budget $1,230,749.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents** (Not applicable)
- **Significant changes in use or care of human subjects** (No significant changes)
- **Significant changes in use or care of vertebrate animals.** (Not applicable)
- **Significant changes in use of biohazards and/or select agents** (Not applicable)

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

- **Journal publications.**

DoD publication clearance was obtained from USA, USAF, TATRC for our first manuscript submitted to JMIR Research Protocols for peer review DEC 2016; JMIR Research Protocols approved manuscript for submission on 12 FEB 2017; JMIR Research Protocols manuscript published on 6 MAR 2017: *Enhancing mHealth Technology in the patient centered medical home environment to activate Type 2 diabetes patients: A multi-site feasibility study protocol;* http://www.researchprotocols.org/2017/3/e38/

- **Books or other non-periodical, one-time publications.** (Not applicable)
- **Other publications, conference papers, and presentations.**

2016 AMSUS Annual Continuing Education Meeting - Poster #1 – presented 11/29/16, National Harbor, Maryland - "New Biometric Data Collection, Analysis and Visualization in the DoD's Mobile Health Care Environment"; Authors: Ron Gimbel, PhD, Clemson University; Jeanette Little, MS, TATRC; Terry Newton, MD, OTSG – USA.

2016 AMSUS Annual Continuing Education Meeting - Poster #2 – presented 11/29/16, National Harbor, Maryland – "Enhancing mHealth Technology in the DoD's PCMH Environment to Activate

Type 2 Diabetes Patients; Authors: Ron Gimbel, PhD; Joel Williams, PhD; Liwei Chen, MD, PhD; Cheryl Dye, PhD; Karen Edwards, Med.; Jeanette Little, MS, Terry Newton, MD

Poster delivered for American Academy of Health Behavior Scientific Meeting, Tucson, AZ; *Improving Diabetes Self-management through Messages Tailored to Patient Activation levels*; delivered 19-22 MAR 2017.

Presentation approved for the Military Health System Research Symposium, Kissimmee, FL; *Mobile Health Apps in the Medical Theater of Operation – Exploring the Usability of a Mobile Application for Improving Chronic Disease Self-management in the Patient Centered Medical Home Environment.* AUG 2017.

- **Website(s) or other Internet site(s) –** Nothing to report during this reporting period
- **Technologies or techniques**

  The Telemedicine and Advanced Technology Research Center (TATRC), in partnership with Clemson University, are expanding the capabilities of the Mobile Health Care Environment (MHCE) to support enhanced communication and patient self-management behaviors in Type 2 diabetes care.

  In fiscal year 2017/18 the TATRC-Clemson University accomplished the following:

  - Development of initial prototype mCare application interface
  - Pilot testing of the initial prototype mCare application interface
  - User focus group usability testing of the mCare application interface
  - Data analysis of the SUS scoring on the user focus group testing
  - Refinement of the mCare application interface based on pilot and focus group usability testing (PowerPoint slides are attached)
  - Development of the mCare provider portal interface
  - Pilot testing of the mCare provider portal interface
  - Refinement of the mCare provider portal interface (PowerPoint slides are attached)
  - Establishment of normalized fitness tracker date using the Validic API to the MHCE system.
  - Ordering and distribution of the end user equipment to the two study site Research Associates.
  - Development of training manuals and end user guides
  - Training to the Research Associates.
  - Technical Support during the enrollment and initial data collection period (ongoing)

- **Inventions, patent applications, and/or licenses** (Not applicable)
- **Other Products** (Not applicable)

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name:	*Ronald W. Gimbel, PhD*
Project Role:	*Principal Investigator*
Nearest person month worked:	2.4
Contribution to Project:	*Dr. Gimbel has performed work as the Principal Investigator.*
Name:	*Karen Edwards*
Project Role:	*Research Associate*
Nearest person month worked:	*12*
Contribution to Project:	*Karen oversees all aspects of the study along with Dr. Gimbel.*
Name:	*Jennie Moss*
Project Role:	*Senior Research Associate*
Nearest person month worked:	12
Contribution to Project:	*Jennie oversees all aspects of the study located at Nellis AFB.*
Name:	*Kristy Crawford*
Project Role:	*Research Associate*
Nearest person month worked:	*12*
Contribution to Project:	*Kristy oversees all aspects of the study located at Nellis AFB.*

Name:	*Marie Rempola Hing*
Project Role:	*Senior Research Associate*
Nearest person month worked:	12
Contribution to Project:	*Marie oversees all aspects of the study at Madigan AMC.*

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?** Nothing to report for this reporting period
- **What other organizations were involved as partners?**
  - **Organization Name: TATRC**
  - **Location of Organization:** Building 38711, Fort Gordon, Georgia 30905-5650
  - **Partner's contribution to the projec**t
    - **Financial support –** n/a
    - **In-kind support** – n/a
    - **Facilities** – n/a
    - **Collaboration** – TATRC's *staff is working with Clemson University project staff on the project.*
    - **Personnel exchanges** – n/a
    - **Other – n/a**

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:** No applicable for this reporting period
- **QUAD CHART:** see Appendix

9. **APPENDICES:**

AMSUS Poster #1

AMSUS Poster #2

American Academy of Health Behavior Scientific Meeting Poster

Presentation Outline approved for the Military Health System Research Symposium

Manuscript copy

Power Point sample slides of the mCare patient product

PowerPoint samples slides of the mCare provider portal interface

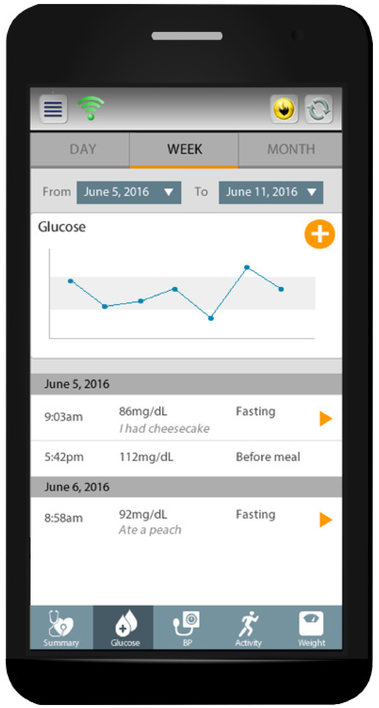
Quad Chart thru 7/31/17

Enhancing mHealth Technology in the DoD's PCMH Environment to Activate Type 2 Diabetes Patients

Ronald Gimbel, PhD[1], Joel Williams, PhD[1], Liwei Chen, PhD, MD[1], Cheryl Dye, PhD[1], Karen Edwards, MS[1], Jeanette Little, MS[2], Terry Newton, MD[3]

LEARNING OBJECTIVES:

1. The learner will be able to identify valid and reliable socio-behavioral survey instruments used to measure patient activation and self-care activities.
2. The learner will be able to recognize common periph eral devices used in chronic care patient self-manage ment for diabetes care.
3. The learner will recognize the need and challenge of establishing clinical and patient safety algorithms in the use of biometric data.
4. The learner will be able to explain desired data visual ization options in mobile health projects that might in

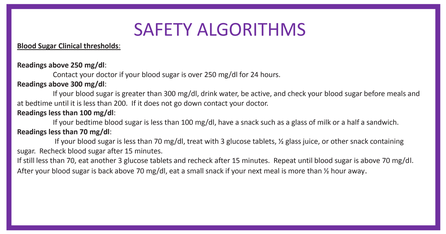


fluence patient use and clinical workflow.

©2016 Insignia Health. Patient Activation Measure® (PAM®) Survey Levels. All rights reserved.

BACKGROUND:

Mobile health (mHealth) technology in the care of patients with diabetes has demonstrated varying degrees of effectiveness. In this project we seek to incorporate the most promising capabilities of mHealth technology in a Patient-Centered Medical Home (PCMH) to support the activation of patients with Type 2 diabetes. We anticipate that greater patient activation will lead to improved self-care behaviors and outcomes (clinical and health service).



SAFETY ALGORITHMS

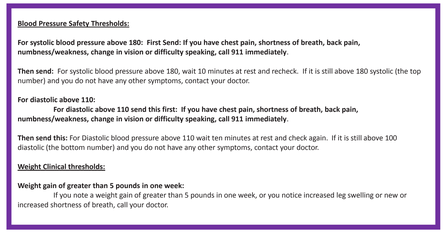
Blood Sugar Clinical thresholds:

Readings above 250 mg/dl:
Contact your doctor if your blood sugar is over 250 mg/dl for 24 hours.

Readings above 300 mg/dl:
If your blood sugar is greater than 300 mg/dl, drink water, be active, and check your blood sugar before meals and at bedtime until it is less than 200. If it does not go down contact your doctor.

Readings less than 100 mg/dl:
If your bedtime blood sugar is less than 100 mg/dl, have a snack such as a glass of milk or a half a sandwich.

Readings less than 70 mg/dl:
If your blood sugar is less than 70 mg/dl, treat with 3 glucose tablets, ½ glass juice, or other snack containing sugar. Recheck blood sugar after 15 minutes.
If still less than 70, eat another 3 glucose tablets and recheck after 15 minutes. Repeat until blood sugar is above 70 mg/dl.
After your blood sugar is back above 70 mg/dl, eat a small snack if your next meal is more than ½ hour away.



Blood Pressure Safety Thresholds:

For systolic blood pressure above 180: First Send: If you have chest pain, shortness of breath, back pain, numbness/weakness, change in vision or difficulty speaking, call 911 immediately.

Then send: For systolic blood pressure above 180, wait 10 minutes at rest and recheck. If it is still above 180 systolic (the top number) and you do not have any other symptoms, contact your doctor.

For diastolic above 110:
For diastolic above 110 send this first: If you have chest pain, shortness of breath, back pain, numbness/weakness, change in vision or difficulty speaking, call 911 immediately.

Then send this: For Diastolic blood pressure above 110 wait ten minutes at rest and check again. If it is still above 100 diastolic (the bottom number) and you do not have any other symptoms, contact your doctor.

Weight Clinical thresholds:

Weight gain of greater than 5 pounds in one week:
If you note a weight gain of greater than 5 pounds in one week, or you notice increased leg swelling or new or increased shortness of breath, call your doctor.

METHOD:

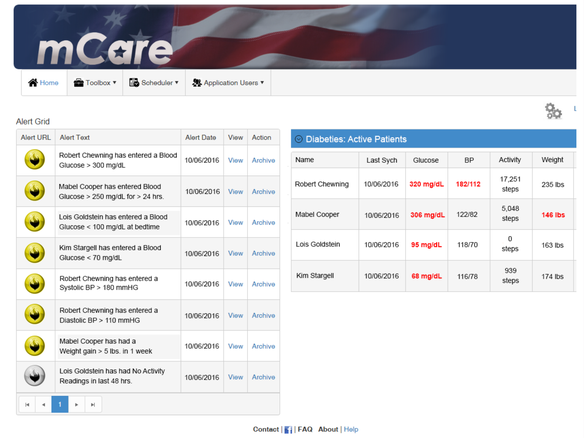
Formal single-blinded 12-month feasibility study conducted within the PCMH environment of two Military Treatment Facilities (MTFs). Study includes enhancement of the MHCE to add mobile patient devices and collection, analysis, and visualization of biometric data as well as tailored behavioral messages aligned with Patient Activation Measure (PAM®) scores. Study is preceded (2016) by a user-centered design phase that included both patients and PCMH clinicians. The formal study will recruit 240 patients (120 intervention, 120 control) who meet inclusion criteria. Primary measures of interest include PAM® and Summary of Diabetes Self-Care Activities (SDSCA) scores and clinical measures. The study was advised by a clinician-driven team and development team. Algorithms for safety and behavioral reinforcement are also included.

Sample of Tailored Behavioral Messages (by PAM level)

PAM Level	Sample Behavioral Message based on PAM Level of Activation
1	Managing diabetes can seem overwhelming at times. Just remember that you don't have to do it alone, there are people who can help.
2	By eating well-balanced meals you can learn to manage diabetes.
3	Ask yourself if you are really hungry or if you want to eat because you are feeling stressed, bored or frustrated.
4	Eating during times of stress is very common. Keep this in mind when stressful events come your way so that you can have a plan to avoid overeating.

DISCUSSION:

Research benefits include improved understanding of how to advance three joint PCMH principles (coordination of care, improved quality and safety, and enhanced access to care) through the use of mobile technology. We will also focus on integrated mHealth technology into the PCMH workflow, as well as exploring how to use mHealth technology in



the activation of patients diagnosed with Type 2 diabetes. Finally, we will map patient-centered biomedical data into clinical documentation and a decision support platform useful in chronic care management.

AFFILIATIONS:

[1]Department of Public Health Sciences, Clemson University
[2]Telemedicine and Advanced Technology Research Center
[3] Office of the CMIO, OTSG

DISCLAIMER:

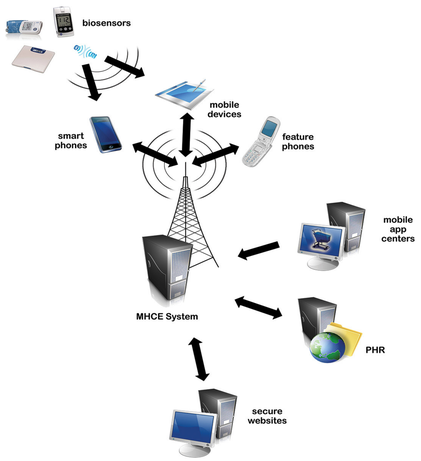
This material is based upon work supported by the U.S. Army Medical Research Acquisition Activity under Contract No. W81XWH-15-C-0070. Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the U.S. Army Medical Research Acquisition Activity.

New biometric data collection, analysis, and visualization in the DoD's Mobile Health Care Environment

Terry Newton, MD[1], Jeanette Little, MS[2], and Ronald Gimbel, PhD[3]

LEARNING OBJECTIVES:

- The learner will be able to identify key steps in adding biometric data to a mobile health care environment.
- The learner will be able to explain desired data visualization options in mobile health projects that might influence patient use and clinical workflow.
- The learner will recognize the need and challenge of establishing clinical and patient safety algorithms in use of biometric data.
- The learner will be able to recognize common peripheral devices used in chronic care patient self-management for diabetes care.



ABSTRACT:

- Telemedicine and Advanced Technology Research Center (TATRC) - Clemson University Partnership
- Expanded the Mobile Health Care Environment (MHCE) system capabilities for Type 2 diabetic self-management behaviors and provider communications
- Research project aimed at enhancing patient activation in the patient centered medical home (PCMH) environment

In fiscal year 2016-17 the TATRC-Clemson University team launched a project Development Advisory Team (DAT) and a Clinical Advisory Team (CAT). The DAT led all technical research (e.g. DoD information security & privacy requirements, data mapping requirements) and related design and process requirements (e.g. interface with wireless communication providers, visualization capabilities and options, data analytic structure) while seeking regular feedback from the CAT. The CAT, populated by MHS clinicians, academicians, and research associates, established clinical and safety thresholds and provided clinician preferences on optimal data visualization and clinical workflow. To ensure the MHCE thresholds were grounded in evidence, CAT members compared them to clinical practice guidelines, systematic reviews, and other biomedical manuscripts.

SAFETY ALGORITHMS

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Contact your doctor if your blood sugar is over 250 mg/dl for 24 hours.
Readings above 300 mg/dl:
If your blood sugar is greater than 300 mg/dl, drink water, be active, and check your blood sugar before meals and at bedtime until it is less than 200. If it does not go down contact your doctor.
Readings less than 100 mg/dl:
If your bedtime blood sugar is less than 100 mg/dl, have a snack such as a glass of milk or a half a sandwich.
Readings less than 70 mg/dl:
If your blood sugar is less than 70 mg/dl, treat with 3 glucose tablets, ½ glass juice, or other snack containing sugar. Recheck blood sugar after 15 minutes.
If still less than 70, eat another 3 glucose tablets and recheck after 15 minutes. Repeat until blood sugar is above 70 mg/dl.
After your blood sugar is back above 70 mg/dl, eat a small snack if your next meal is more than ½ hour away.

Blood Pressure Safety Thresholds:

For systolic blood pressure above 180: First Send: If you have chest pain, shortness of breath, back pain, numbness/weakness, change in vision or difficulty speaking, call 911 immediately.

Then send: For systolic blood pressure above 180, wait 10 minutes at rest and recheck. If it is still above 180 systolic (the top number) and you do not have any other symptoms, contact your doctor.

For diastolic above 110:
For diastolic above 110 send this first: If you have chest pain, shortness of breath, back pain, numbness/weakness, change in vision or difficulty speaking, call 911 immediately.

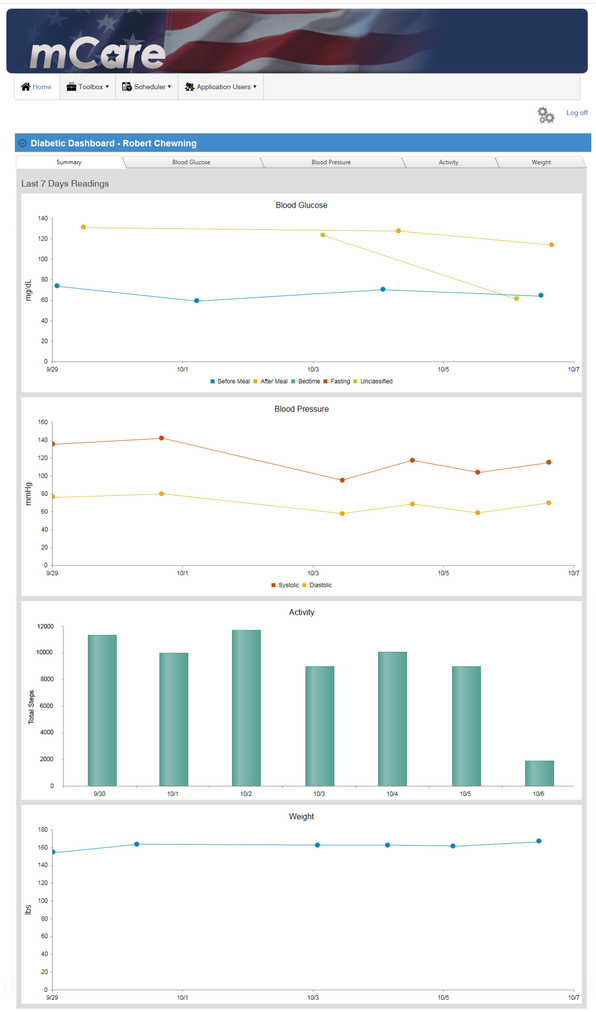
Then send this: For Diastolic blood pressure above 110 wait ten minutes at rest and check again. If it is still above 100 diastolic (the bottom number) and you do not have any other symptoms, contact your doctor.

Weight Clinical thresholds:

Weight gain of greater than 5 pounds in one week:
If you note a weight gain of greater than 5 pounds in one week, or you notice increased leg swelling or new or increased shortness of breath, call your doctor.

The project included three major components: data collection, data analysis, and data visualization.

- Primary data collection issues included DoD regulatory requirements, data mapping from peripheral devices, patient entry of free-text data, and agreements with wireless communication providers.



- Data analysis issues included temporal issues (e.g. in tra-day measures) regarding when to apply computational tasks, establishing minimum thresholds for patient safety, identifying when biomedical data should trigger behavioral reinforcement, and other reporting tasks.
- Data visualization issues included assessing visualization placement within the screen (differing devices), presentation options for patients (e.g. presenting data aggregation, temporal options, options on averaging or raw presentation).

Patient devices include an approved Wi-Fi/Bluetooth-enabled scale, blood pressure cuff, glucometer, and an activity monitor. The product was subjected to user-centered usability testing and is included in a large multi-site feasibility study within the MHS.

mCare Bluetooth Devices

AFFILIATIONS:

[1] Office of the CMIO, OTSG, U.S. Army
[2]Telemedicine and Advanced Technology Research Center
[3]Department of Public Health Sciences, Clemson University

DISCLAIMER:

Army Medical Research Acquisition Activity under Contract No. W81X-WH-15-C-0070. Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the U.S. Army Medical Research Acquisition Activity.

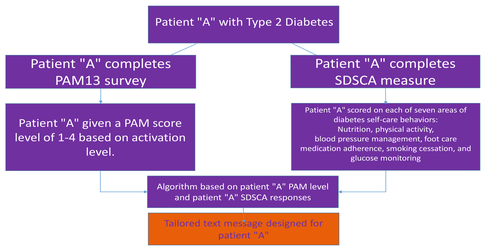
Improving Diabetes Self-Management Through Messages Tailored to Patient Activation Levels

Cheryl Dye, PhD; Sarah Griffin, PhD; Rachel Mayo, PhD; Joel Williams, PhD; Karen Edwards, MS; Jennie Moss, RN; Marie HIng, MS; Karyn Jones, PhD; Ronald Gimbel, PhD

BACKGROUND

Mobile health (mHealth) technology in the care of patients with diabetes has demonstrated varying degrees of effectiveness. In this project, we seek to incorporate the most promising capabilities of mHealth technology in a Patient-Centered Medical Home (PCMH) to support the activation of patients with Type 2 diabetes. We anticipate that greater patient activation will lead to improved self-care behaviors and health outcomes. Algorithms based on scores from the Patient Activation Measure® (PAM®)[1] and the Survey for Diabetes Self Care Activities (SDSCA)[2] instrument trigger the release of messages tailored to the PAM® and the SDSCA scores in the form of texts to intervention individuals at two military bases. (see Figure 1)

FIGURE 1

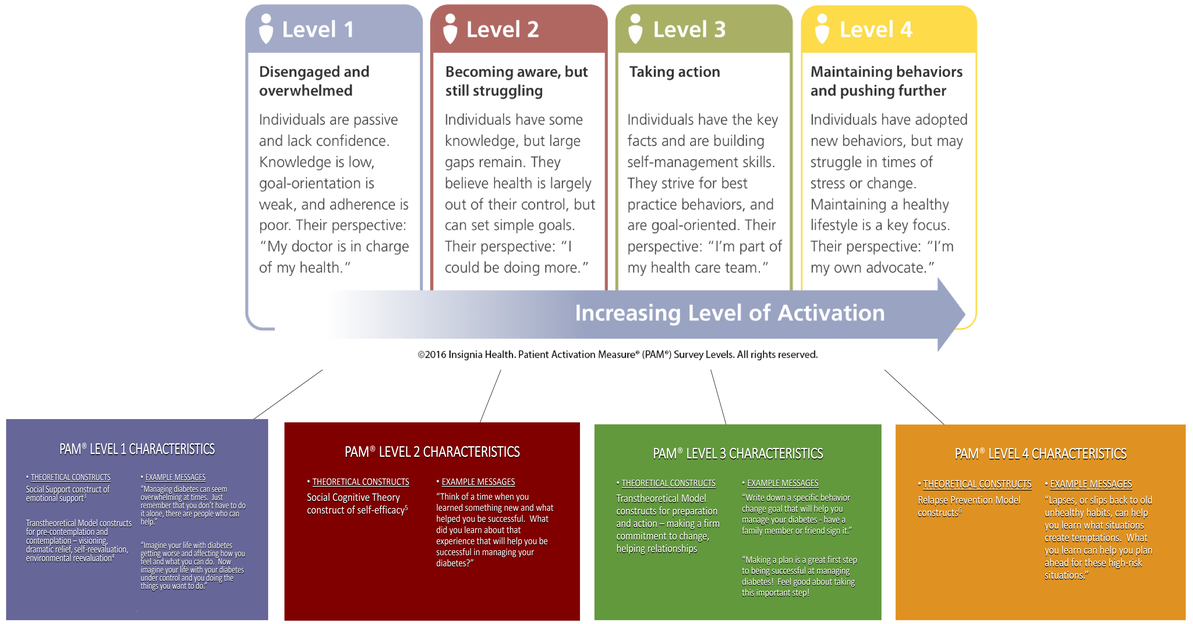


METHODS

A multi-stage message development process was guided by patient activation levels and theoretical constructs relevant to those levels.

Step One: Researchers developed messages tailored for each of the four PAM® score levels and five diabetes self-care behaviors measured by the SDSCA: nutrition, physical activity, foot care, smoking cessation, and glucose monitoring.

Step Two: Messages were assessed by two-person teams for content accuracy, reading level, and message appropriateness for PAM® level. Messages were then revised based on this review process. A clinical advisory team consisting of clinicians and researchers reviewed and approved the messages for clinical relevance and content.



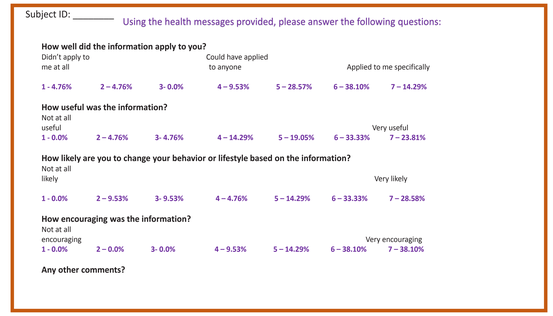
Step Three: A pre-test (n=21) of the messages with a similar population as those targeted for the larger study was adminstered. Each person was provided with a random sample of five messages based on their PAM® Level. They were then asked four close-ended questions and one open-ended question about the messages. (See Figure 2)

Step Four: Researchers reviewed PAM® level specific messages and rated them as acceptable, questionable or unacceptable based on appropriateness for PAM® level, behavioral theory construct, reading level and content accuracy. Messages were then revised based on this review process.

RESULTS AND DISCUSSION

The multi-stage message development process allowed for triangulation review findings which yielded a set of 379 PAM® level appropriate messages. At each step in the process, messages were reviewed and revised based on research team member feedback (Stages Two and Four) or by potential study participant feedback (Stage Three). Overall, the first two steps in the process produced messages with a high degree of acceptability by people very similar to the study population (See Figures 2 and 3). Pre-test participants found the messages to be encouraging, useful, applicable, and impactful. (see Figure 3) This indicates a high level of credibility with regard to application of the theoretical constructs within the messages. "Tailoring should be viewed as complementary to the counseling activities of health educators and others, a potentially powerful tool to enhance their work, not replace it."[7]

FIGURE 2


Subject ID: _____ Using the health messages provided, please answer the following questions:

How well did the information apply to you?
Didn't apply to me at all — Could have applied to anyone — Applied to me specifically
1 - 4.76% 2 – 4.76% 3- 0.0% 4 – 9.53% 5 – 28.57% 6 – 38.10% 7 – 14.29%

How useful was the information?
Not at all useful — Very useful
1 - 0.0% 2 – 4.76% 3- 4.76% 4 – 14.29% 5 – 19.05% 6 – 33.33% 7 – 23.81%

How likely are you to change your behavior or lifestyle based on the information?
Not at all likely — Very likely
1 - 0.0% 2 – 9.53% 3- 9.53% 4 – 4.76% 5 – 14.29% 6 – 33.33% 7 – 28.58%

How encouraging was the information?
Not at all encouraging — Very encouraging
1 - 0.0% 2 – 0.0% 3- 0.0% 4 – 9.53% 5 – 14.29% 6 – 38.10% 7 – 38.10%

Any other comments?

FIGURE 3

Pilot testing results of health messages based on 7-point Likert Scale

80.96% felt the messages were in the upper range (5-7) of applying to them specifically.

76.19% felt the messages were in the upper range (5-7) of being useful.

76.20% felt the messages were in the upper range (5-7) in being likely to cause them to change their behavior.

90.49% felt the messages were in the upper range (5-7) of being encouraging.

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DISCLAIMER:
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CLEMSON UNIVERSITY

Exploring the Usability of a Mobile Application for Improving Chronic Disease Self-Management in the Patient Centered Medical Home Environment

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Presentation Outline

- Provide an overview of larger study

- Describe Phase 1 research:
  - Background
  - Objectives
  - Methods
  - Findings

Research Group Structure

- Government, Academia, Industry partnership
  - Development Advisory Board
  - Clinical Advisory Team
  - Intervention Team

Acknowledgements – Phase 1 Team

- Sarah F. Griffin, MPH, Ph.D. [1]
- Karen W. Edwards, MEd [1]
- Jennie B. Moss, RN [1,2]
- Marie E. Hing, MS [1,3]
- Jeanette R. Little, MS [4]
- Ronald Gimbel, Ph.D. [1] (Principal Investigator)

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[2] Mike O'Callaghan Federal Medical Center, Las Vegas, NV

[3] Madigan Army Medical Center, Tacoma, WA)

[4] US Army Telemedicine and Advanced Technology Research Center, Fort Gordon, GA

Background – Research Study

- Multi-site Military Health System study
  - U.S. Department of Defense W81XWH-15-C-0070 Gimbel (PI) "Enhancing mHealth Technology in the PCMH Environment to Activate Chronic Care Patients" 08/15 – 01/18
  - Mike O'Callaghan Federal Medical Center (NV)
  - Madigan Army Medical Center (WA)

- Phase 1: Utilized a participatory approach in guiding adaptations of a health system application, called mCare.

- Phase 2: Feasibility study where patients are randomized to biosensors only vs. biosensors + mCare interface + tailored messaging

Background – Biosensors & mCare

- Glucometer: My GlucoHealth

- Blood Pressure Monitor: A&D

- Weight Scale: A&D

- Activity Monitor:
  - Fitbit Charge (wrist)

Menu
iPad
1:59 PM
95%
My Devices
Last 7 Days
Announcements
Health Tips
Safety Alerts
Blood Glucose
mg/dL
140
120
100
80
60
40
20
0
9/28
9/29
9/30
10/1
10/2
10/3
10/4
Before Meal
After Meal
Fasting
Unclassified
Target Ranges
Blood Pressure
mmHg
160
140
120
100
80
60
40
Systolic
Diastolic
Physical Activity
Active Steps
14000
12000
10000
8000
6000
4000
0
33
0
0
0
0
0
More
Summary
Glucose
BP
Activity
Weight

Home | Toolbox ▾ | Scheduler ▾ | Application Users ▾ | Manage User Access ▾ | Administrator ▾

Log off

Alert Grid

Alert URL	Alert Text	Alert Date	View	Action
	Robert Chewning has entered a Blood Glucose > 300 mg/dL	10/06/2016	View	Archive
	Mabel Cooper has entered Blood Glucose > 250 mg/dL for > 24 hrs.	10/06/2016	View	Archive
	Lois Goldstein has entered a Blood Glucose < 100 mg/dL at bedtime	10/06/2016	View	Archive
	Kim Stargell has entered a Blood Glucose < 70 mg/dL	10/06/2016	View	Archive
	Robert Chewning has entered a Systolic BP > 180 mmHG	10/06/2016	View	Archive
	Robert Chewning has entered a Diastolic BP > 110 mmHG	10/06/2016	View	Archive
	Mabel Cooper has had a Weight gain > 5 lbs. in 1 week	10/06/2016	View	Archive
	Lois Goldstein has had No Activity Readings in last 48 hrs.	10/06/2016	View	Archive

|◂ ◂ 1 ▸ ▸|

Diabeties: Active Patients

Name	Last Sych	Glucose	BP	Activity	Weight	
Robert Chewning	10/06/2016	320 mg/dL	182/112	17,251 steps	235 lbs	View
Mabel Cooper	10/06/2016	306 mg/dL	122/82	5,048 steps	146 lbs	View
Lois Goldstein	10/06/2016	95 mg/dL	118/70	0 steps	163 lbs	View
Kim Stargell	10/06/2016	68 mg/dL	116/78	939 steps	174 lbs	View

Phase 1 Objective & Methods

- Utilize a participatory approach to engage Type 2 diabetics, and the clinicians who treat them, in guiding adaptations of the mCare interface to be used in Phase 2 of this study.

- Mixed methods approach:

Quantitative
- Patient task observations
- Open-ended questions during usability testing to capture Patient thoughts

Quantitative
- Patient + Clinician feedback
- Patient task completion notes

Methods – Design

- Science Panel on Interactive Communication and Health (Robinson et al., 1998)
- International Organization for Standardization (ISO) 9241-11 Usability framework : usability definitions and evaluation metrics
- Georgsson & Staggers (2016) model
- Mixed methods evaluation (QUAN + QUAL)

Methods – Context of Use (Patients)

- **Users:** Describe relevant characteristics of the users.
- **Tasks:** Specific activities (device interactions) that will be required of users.
- **Equipment:** Hardware, software and peripheral devices (My GlucoHealth glucometer, A&D blood pressure monitor, A&D weight scale, Fitbit Charge).
- **Environment:** Relevant characteristics of the testing environment including: technical (WiFi), and physical (testing space).

Methods – Usability Metrics (Patients)

- **Effectiveness:** Extent to which the user can achieve a goal with accuracy and completeness.
  - *(1) the degree of task completion AND*
  - *(2) total number of errors per task*

- **Efficiency:** Level of effort and resource usage which is required by the user in order to achieve a goal in relation to accuracy and completeness.
  - *Timed each individual task and compute average time for each task across users.*

- **Satisfaction:** Extent to which users are free from discomfort, and their attitudes towards the use of the product.
  - *Single Ease Question (SEQ – Sauro & Dumas, 2009)*
  - *Open-ended questions (developed by Phase 1 Team)*
  - *System Usability Scale (SUS – Sauro & Lewis, 2012)*

Methods – Usability Tasks (Patients)

- Login and System navigation
- Goal setting
- Specific tasks for each biosensor:
  - Blood pressure (manual entry, Bluetooth sync, graphs)
  - Blood sugar (manual entry, graphs)
  - Weight scale (manual entry, Bluetooth sync, graphs)
  - Fitbit (graph interpretation only)

Methods – Usability (Clinicians)

- Focus groups
  - Physicians and Clinical Staff
    - Recorded
    - Field notes
- Feedback on:
  - Perceived usability for patient
  - Workflow issues / concerns
  - Message content - system alerts, patient reminders
  - Backend portal (doctor's view)

Findings – Patients

- All diabetics indicated that mCare would “help them manage their diabetes” and give their healthcare provider a “better report of their health.” As expected, patients rated navigation tasks as less difficult and peripheral device tasks, e.g., syncing, as more difficult.

- Diabetics committed fewer errors with basic navigation tasks and more with peripheral devices. Further, a higher proportion of diabetics made errors with external device tasks.

- Diabetics and clinicians alike suggested minor changes regarding the look and function of the application, e.g., adding more color and contrast, making buttons larger.

White (n=14, 70%) African-American (n=2, 10%) Native Hawaiian/Pacific Islander (n=2, 10%) Asian (n=2, 10%)

Male (n=14, 70%) Female (n=6, 30%)

Findings – Patients

- Comfort with using apps or technology (5 point scale)
  - *Means*, All: 3.3 (Madigan: 2.8 , Nellis: 3.8)

- Task completion times, *Range*: 3.29 sec - 249.45 sec

- Single Ease Use Question (7 point scale)
  - *Range of Means:* 2.8 – 6.6

- System Usability Scale (SUS)
  - SUS overall*, Mean (SD)*: 83.8 (14.9) = A+
  - Usability Sub Factor*, Mean (SD)*: 86 (13.4) = A+
  - Learnability Sub Factor*, Mean (SD)*: 75 (27.5) = A-

Findings – Clinicians

- Overall, Clinicians were pleased with the mCare system and optimistic about both the backend portal ("doctor's view") and application utility for patients.

- Clinicians also had additional suggestions specifically related to alerts, e.g., parameters for alerts sent to patients, color coding alerts for ease of clinician review.

- Patient and Clinician suggestions were reviewed and incorporated as adaptations by the technology team as allowed by system constraints.

19 Physicians (2 DO, 17 MD) ; 1-19 years experience

14 Clinical staff (FNP, nurses, disease managers, pharmacists) ; 4-39 years experience

TATRC Recommendations

- 29 specific recommendations were made to TATRC
  - Only 4 could NOT be completed
    - additional colors (limited colors available)
    - remove signal and refresh buttons (part of the base system)
    - alert icons (limited icon choices available)
    - automatic syncing of devices (system cannot do this)
  - >86% of recommended changes WERE made
  - Usability testing is CRITICAL in understanding the needs of end users and will provide a more meaningful interface for Phase 2 participants

Major Recommendations/Changes

Patients

- increase size of icons
- separate glucose graphs (no overlay)
- increase font size
- allow past dates for manual entry

Clinicians

- change default blood glucose entry to unclassified
- define "after meal" glucose as ≥120 minutes post meal
- simplify safety alerts (with Clinical Advisory Team)
- add icons beside safety alerts
- add patient target ranges on graphs

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Protocol

Enhancing mHealth Technology in the Patient-Centered Medical Home Environment to Activate Patients With Type 2 Diabetes: A Multisite Feasibility Study Protocol

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Abstract

Background: The potential of mHealth technologies in the care of patients with diabetes and other chronic conditions has captured the attention of clinicians and researchers. Efforts to date have incorporated a variety of tools and techniques, including Web-based portals, short message service (SMS) text messaging, remote collection of biometric data, electronic coaching, electronic-based health education, secure email communication between visits, and electronic collection of lifestyle and quality-of-life surveys. Each of these tools, used alone or in combination, have demonstrated varying degrees of effectiveness. Some of the more promising results have been demonstrated using regular collection of biometric devices, SMS text messaging, secure email communication with clinical teams, and regular reporting of quality-of-life variables. In this study, we seek to incorporate several of the most promising mHealth capabilities in a patient-centered medical home (PCMH) workflow.

Objective: We aim to address underlying technology needs and gaps related to the use of mHealth technology and the activation of patients living with type 2 diabetes. Stated differently, we enable supporting technologies while seeking to influence patient activation and self-care activities.

Methods: This is a multisite phased study, conducted within the US Military Health System, that includes a user-centered design phase and a PCMH-based feasibility trial. In phase 1, we will assess both patient and provider preferences regarding the enhancement of the enabling technology capabilities for type 2 diabetes chronic care management. Phase 2 research will be a single-blinded 12-month feasibility study that incorporates randomization principles. Phase 2 research will seek to improve patient activation and self-care activities through the use of the Mobile Health Care Environment with tailored behavioral messaging. The primary outcome measure is the Patient Activation Measure scores. Secondary outcome measures are Summary of Diabetes Self-care Activities Measure scores, clinical measures, comorbid conditions, health services resource consumption, and technology system usage statistics.

Results: We have completed phase 1 data collection. Formal analysis of phase 1 data has not been completed. We have obtained institutional review board approval and began phase 1 research in late fall 2016.

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Conclusions: The study hypotheses suggest that patients can, and will, improve their activation in chronic care management. Improved activation should translate into improved diabetes self-care. Expected benefits of this research to the scientific community and health care services include improved understanding of how to leverage mHealth technology to activate patients living with type 2 diabetes in self-management behaviors. The research will shed light on implementation strategies in integrating mHealth into the clinical workflow of the PCMH setting.

Trial Registration: ClinicalTrials.gov NCT02949037. https://clinicaltrials.gov/ct2/show/NCT02949037. (Archived by WebCite at http://www.webcitation.org/6oRyDzqei)

(JMIR Res Protoc 2017;6(3):e38) doi:10.2196/resprot.6993

KEYWORDS

mHealth; diabetes mellitus; patient activation; patient-centered medical home; patient centered care; eHealth; health information

Introduction

Diabetes mellitus is a chronic disease with high rates of disability, impaired quality of life, and premature death [1-4]. The prevalence of type 2 diabetes is increasing at an alarming rate in the United States; in 2013, the estimated number of patients was between 20 million and 27 million, or about 7% to 10% of the adult population [2,3]. Research suggests that, if current trends continue, diabetes will be diagnosed in 1 in 3 adults in the United States by 2050 [4,5]. Diabetes is the leading cause of blindness, nontraumatic amputations, and adult renal failure, and reduces life expectancy by 5-10 years [2]. The individual symptom burden (eg, chronic pain, neuropathy, depression, and physical disability) is substantial and significantly increases in the older adult population [1]. In the United States, an average individual with diabetes incurs medical expenditures of about US $13,700 a year, of which about US $7900 is attributable to diabetes [4]. This represents an expenditure about 2.3 times greater than that for a diabetes-free individual [4].

Numerous primary care-based efforts have been aimed at reducing both the disease burden on individuals and the cost of diabetes care. A contemporary strategy is the management of patients with diabetes within the context of the patient-centered medical home (PCMH) setting. A key PCMH principle is the appropriate use of information technology to support optimal patient care, performance measurement, patient education, and enhanced communication [6]. Several case studies from various US health systems show the benefit of the PCMH model to improved diabetes care [7]. There is published evidence on the positive impact of PCMH-based care in psychosocial outcomes of patients with diabetes [8].

The potential of mHealth technologies in the care of patients with diabetes and other chronic conditions has captured the attention of clinicians and researchers. Efforts to date have incorporated a variety of tools and techniques, including Web-based portals [9-11], short message service (SMS) text messaging [9,12-14], remote collection of biometric data [12,15], electronic coaching [14], electronic-based health education [13], secure email communication between visits [16-18], electronic collection of lifestyle and quality-of-life surveys, and personal health records (PHRs). Each of these tools, used alone or in combination, has demonstrated varying degrees of effectiveness. Some of the more promising results have been demonstrated using regular collection of biometric devices (eg, glucometers, activity monitors) [12], SMS text messaging [12-14], secure email communication with clinicians and clinical teams [9,16,17], and regular reporting of quality-of-life variables aligned with decision support. In this study, we seek to incorporate many of the most promising mHealth capabilities in a PCMH workflow led by a clinical advisory team. We aim to address underlying technology needs and gaps related to the use of mHealth technologies and the activation of patients with type 2 diabetes.

The Concept of Patient Activation

Self-management for patients with type 2 diabetes and other chronic conditions includes following complex treatment regimens, monitoring chronic conditions, and making lifestyle changes [19-22]. The chronic care model suggests that activated patients are better able to function in the role of self-manager [21,23]. An activated patient has the motivation, confidence, and skills necessary to enact behavioral changes and make health-related decisions [24-27]. These patients ask questions and collaborate with their health care provider [19,26-28]. Research shows that activated patients have more positive clinical outcomes, are more likely to receive preventive care, and have lower health care-related costs [24,26,29].

A recommended strategy in patient activation is the concept of "preactivating" patients prior to clinical encounters [20,30]. The concept incorporates active targeted communication and follow-up from the health care team [30]. Interventions to include educational programs [31], care coaching [32], and motivational interviewing [33] have been attempted to improve patient activation with varied success [34]. However, these efforts have infrequently been tailored to potential intrinsic differences in how the patients approach their disease. Theoretically, research suggests that patient activation can be increased [19,35-37]. Conceptualizing activation as a dynamic variable allows researchers to target this motivating factor that can potentially influence health behaviors [21,24,38,39].

Previous Research on Patient Portals, Personal Health Records, Patient Activation, and Improved Outcomes

Federal legislation and movement toward patient centeredness in the United States has fueled interest in providing patients with access to their health information, enhanced communication with clinical environments, and greater emphasis on self-care [40-43]. Early research on portal and PHR use and patient activation provided mixed results. Several studies reported a positive significant relationship between use of portals and

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PHRs and activation of patients [41,43-45], while other studies did not realize a significant finding [40,46,47]. The design of these published studies prevented any in-depth inquiry into why (or not) portal and PHR use influenced patient activation. Their authors posited a variety of possible factors, including the target patient population [44], time since severe diagnosis or symptoms and episodes [46,47], and patient age (activation being higher in adults than in children) [45]. One study suggested that tailoring a portal or PHR intervention to the patient activation level may optimize intervention efficiency [43].

Early research on increased activation and improved clinical outcomes using patient portal and PHR-based interventions has also provided mixed results. Several studies demonstrated a relationship between increased patient activation and improved intermediate clinical outcomes (eg, hypertension, smoking, body mass index, and glycated hemoglobin [HbA_{1c}]) [48], while a major study did not record a significant finding regarding the same outcomes [42]. It is noteworthy that these early studies did not provide substantial detail on design issues related to the portal or PHR, or whether the intervention included behavioral reinforcement.

User-Centered Design

Design science will inform our development and testing [49,50]. User-centered design will guide development, following participatory design methods to understand more specifically how patients experience diabetes on a daily basis, what clinicians need to know from patients, and how to create a shared communication system for better decision making [51]. Consistent with the guidelines set forth by the Science Panel on Interactive Communication and Health [52], our evaluation design will incorporate the 3 elements of formative, process, and outcome evaluation. Methods include (1) clinician focus groups and in-depth patient interviews to define key knowledge variables that are personally and clinically relevant, (2) iterative usability testing with patients, and (3) iterative observations of the system in clinical settings [53].

Military Health System: An Overview

The US Military Health System (MHS) is a large integrated health system that cares for about 9.39 million beneficiaries through its TRICARE insurance product and its substantial direct care system consisting of tertiary facilities, community hospitals, and clinics globally. Nearly 35% of its beneficiary pool are active duty members and their dependents, with a larger population (about 56%) being retirees and their beneficiaries [54]. The MHS direct care system is robust. Facilities are accredited by the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations), and the MHS operates a dedicated educational infrastructure to support medical and nursing education programs [54]. The MHS has a connecting health information technology infrastructure to support clinical care and clinical operations.

Hypotheses

Hypothesis 1: User-centered design will allow developers to create a patient-centered interactive and tailored mobile technology for use in the PCMH setting.

Hypothesis 2: The use of interactive and tailored mobile technology, the Mobile Health Care Environment (MHCE), employed in the PCMH setting will increase the activation of patients with chronic type 2 diabetes.

Hypothesis 3: The use of interactive and tailored mobile technology in a PCMH setting will increase diabetes self-care activities.

Hypothesis 4: Patients who engage at a higher rate with the interactive and tailored mobile technology in a PCMH setting will realize greater improvement in clinical measures.

The primary goal of the research is to enhance patient activation levels and improve self-management of type 2 diabetes through the use of the MHCE in the PCMH setting. While there are published studies aimed at improving the activation and care of patients with diabetes in the United States, to our knowledge, no study has sought to enhance care of patients with diabetes using a fully comprehensive and adaptable MHCE-like system. We seek to demonstrate improvement in patient activation measured by the Patient Activation Measure (PAM) instrument [21,55]. We believe that, in improving their activation, patients will also realize an improvement in diabetes self-care activities measured by their Summary of Diabetes Self-Care Activities (SDSCA) [56] scores.

Methods

Trial Design

This is a multisite, phased study conducted within the MHS that includes a user-centered design phase and a PCMH-based feasibility trial. In phase 1, we will assess both patient and provider preferences regarding the enhancement of the MHCE technology capabilities for type 2 diabetes chronic care management. The phase 2 research will be a single-blinded (patients only) 12-month feasibility study that will incorporate randomization principles. We will employ a 1:1 allocation ratio between intervention and control.

Inclusion and Exclusion Criteria

Inclusion criteria for patient participation in phase 1 or 2 research are the following: (1) men and women aged 18 years or older, (2) able to understand and read English, (3) enrolled for primary care to one of the target PCMH sites, and (4) having a diagnosis of type 2 diabetes. Additionally, with respect to phase 2 patients, we will seek to recruit a maximum of 120 (per site), with a distribution of patients with PAM levels 1-4, a sample representative of the patients enrolled in the PCMH. We did not derive the 120 per site recruitment numbers from power calculations, but deemed them to be sufficient. Finally, participants for phase 2 must be available for a 12-month study.

Inclusion criteria for clinician participation in phase 1 or 2 research are the following: (1) being a physician, physician assistant, nurse practitioner, or nurse employed at the target site, and (2) providing care for patients with type 2 diabetes.

Exclusion criteria for patient participation in phase 1 or 2 research are the following: (1) pregnant women, (2) non-English-speaking patients, (3) receiving hospice care, (4) having active cancer and receiving treatment with chemotherapy

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or radiation therapy, (5) taking warfarin, (6) recipient of gastric bypass or similar procedure, (7) having a diagnosis of uncontrolled hypothyroidism, (8) having known Cushing syndrome, (9) being treated with oral steroids, (10) having known liver disease, (11) having a current diagnosis of cognitive impairments that would interfere with use of technology, (12) having congestive heart failure, in New York Heart Association functional class 3 or 4, and (13) unable to use a mobile device due to cognitive or physical impairments during initial screening. We exclude pregnant women because they require careful monitoring due to potential medical complications for the woman and unborn child. While some mHealth studies seek to include additional exclusions based on age, educational level, or technical literacy, our research team rejected adding any additional exclusion criteria beyond the 13 listed above. We purposely seek the "average" patient with type 2 diabetes in the target population. Feedback from our clinician investigators and research staff at our clinical sites is encouraging that these patients will be capable of using the intervention technology.

Exclusion criteria for clinician participation in phase 1 or 2 research are the following: (1) not affiliated with the target site, and (2) not providing care for patients with type 2 diabetes.

Participant Enrollment

We will recruit patients via review of the PCMH clinic schedule, referrals from providers, distributed posters and fliers, and population health databases. Potential participants will be prescreened through verification of the inclusion and exclusion criteria based on a medical record review. Interested participants will be scheduled for a screening visit with study staff to provide informed consent and be administered the PAM instrument. Patients' PAM scores will place them in a stratified group, where they will be randomly allocated.

Clinicians practicing in the respective PCMH sites will be invited to participate by word of mouth from the site's principal investigator; this is a convenience sample. The clinician participants who would like to participate in the study will meet with the senior research associate to review the minimal-risk information sheet to be included in the study. For phase 2, clinicians will sign an informed consent form. The clinician participants will not be blinded in the study, nor allocated to intervention or control groups.

Setting and Site Selection

We seek to purposefully assess the MHCE implementation for diabetes care in 2 distinctly different PCMH environments and geographic locations. The risks of attracting very different populations are mitigated by rather comprehensive inclusion and exclusion criteria, which will ensure similarity regarding patient acuity. The patient base includes those on active duty, retirees, and dependents who have typically spent years in the military and have been stationed at various locations. Both of the selected facilities are federal facilities and operated by the MHS.

Madigan Army Medical Center, the US Army's second largest military treatment facility located in Tacoma, Washington, is a tertiary facility with a level II trauma center and robust graduate medical education programs. They serve a patient base of approximately 118,000 patients; about 7500 (or >6%) are living with type 2 diabetes. Of the diabetes population, about 15% are active duty members or their dependents, and about 85% are retirees and their dependents. Over half of the patients with diabetes are 57-76 years of age. The study location within the medical center is a PCMH managed by the Department of Internal Medicine. There are approximately 14,300 patients enrolled in this PCMH supported by a staff of 77 (12 staff physicians; 8 residents) responsible for their care.

Mike O'Callaghan Federal Medical Center is a federal facility in the greater Las Vegas, Nevada area, that serves approximately 47,000 patients; about 4500 (or >9%) are living with type 2 diabetes. Of the diabetes population, about 4% are active duty members or their dependents, and about 96% are retirees and their dependents. Over 72% of the patients with diabetes are in their 60s or older. The study location within the medical center is a PCMH managed by the Department of Family Medicine. There are approximately 7500 patients enrolled in this PCMH supported by a staff of 62 (9 staff physicians; 26 residents) responsible for their care.

Description of the Mobile Health Care Environment

The US Department of Defense (DoD) MHCE system is a secure health information system designed to support health services delivery and mHealth. The MHCE meets all physical and information security mandates, as prescribed by federal law and DoD regulation, for the protection of personal health information and personally identifiable information. The MHCE was developed by the DoD Telemedicine and Advanced Technology Research Center as a platform to support mHealth. Its first major application was to support patient engagement for wounded warriors rehabilitating in their communities. In the study, soldiers on average responded to ≥60% of weekly questionnaires related to behavioral health challenges, posttraumatic stress, or traumatic brain injury [57]. Our study is Telemedicine and Advanced Technology Research Center's second major application. The MHCE is designed to remotely support patients by sending automated reminders, announcements, wellness tips, alerts, and status questionnaires. Figure 1 is a visual example of the graphical user interface that patients will see when accessing the MHCE. In this study, we enhance MHCE capabilities in several ways.

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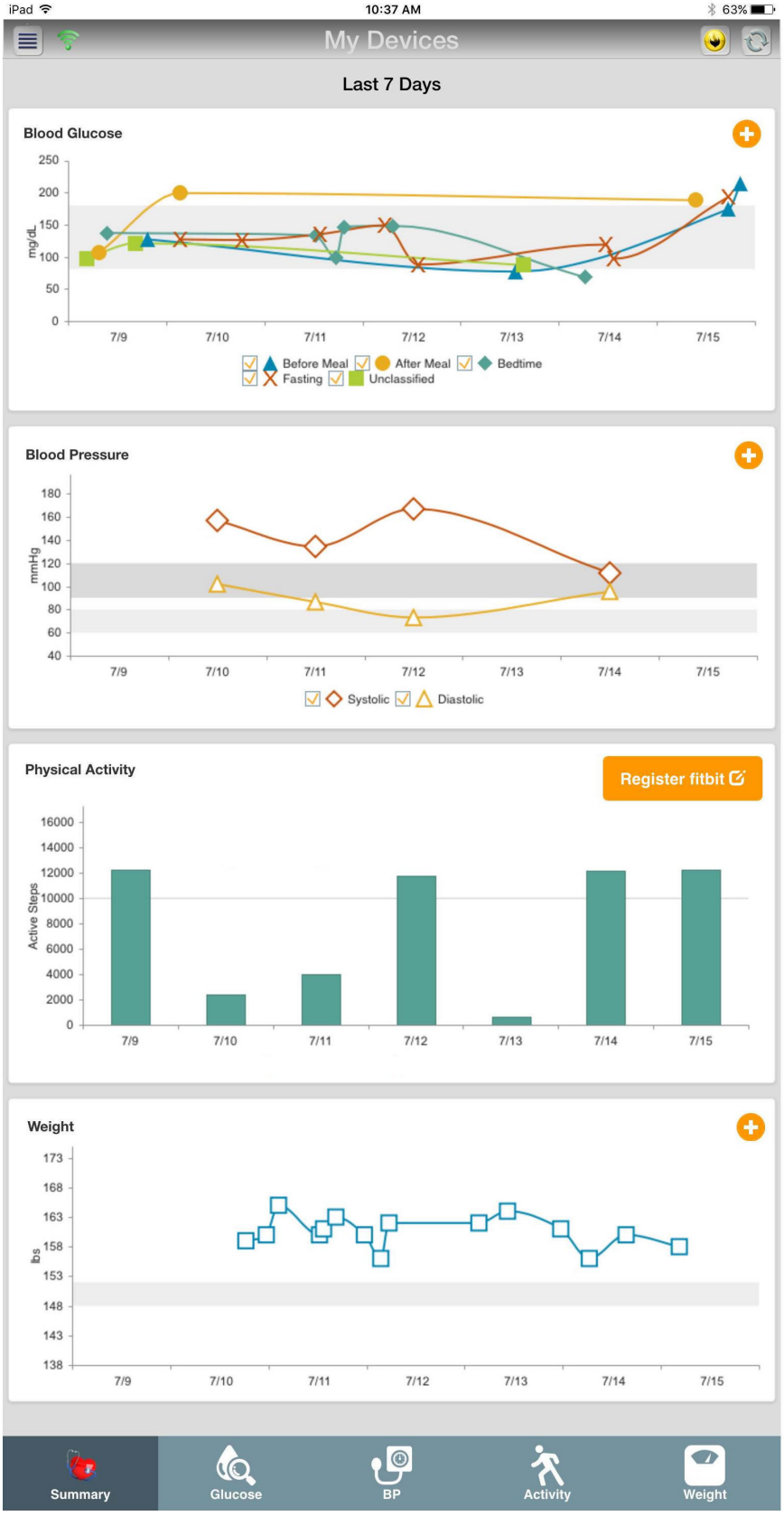
Figure 1. Mobile Health Care Environment home screen (patient view). BP: blood pressure.



Intervention Overview

Our intervention is based on an enhanced MHCE in several ways. First, we add the capability to include collection and visualization of data from Bluetooth-enabled medical devices. This includes mapping data from device output into the MHCE, developing data visualization appropriate for mHealth and clinical care (eg, graphing outcomes, temporal trend patterns), migrating data in an analysis cell, and developing decision-support algorithms that signal safety alerts and need

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for behavioral reinforcement. Devices used in this study include a scale, glucometer, blood pressure reader, and activity monitor. Second, we expand the capacity of the MHCE analysis cell to manage large amounts of data and to conduct both routine reports and research applications. Third, we add patient activation and associated measurement instruments for capturing baseline and ongoing changes to patient activation. Fourth, we expand the MHCE messaging platform that research associates, and later clinical support staff, can use to send tailored behavioral messaging to patients in an effort to influence greater activation and reinforce positive behavior.

The MHCE can be accessed by mobile phones or tablets that use either an IOS or Android platform. The MHCE requires Internet access for patients to sync data from devices (addressed above) to the MHCE backend portal, to receive tailored behavioral messages, or to use other functions. During the study, patients will additionally receive SMS messages with hyperlinks to a separate secure information system platform used for administration and analysis of PAM and SDSCA instruments. MHCE activity, or lack thereof, will be monitored by senior research associates, who can prompt patients via tailored behavioral messages or direct contact.

Tailored Behavioral Messaging

A primary component of the MHCE system is tailored behavioral messaging. Tailored behavioral messages are more likely than generic messages to facilitate health behavior change when they are aligned with individuals' beliefs, lifestyle, demographics, social norms, or interests [58-60].

In this study, the research team has developed behavioral messages tailored for each of the 4 PAM score levels; in total we have developed 360 messages. The messages fall within 9 functional areas common to diabetes care: nutrition, home monitoring, physical activity, blood pressure, foot care, medications, smoking, glucose control, and general behavioral reinforcement. The messages are consistent with general concepts and goals of self-management behaviors consistent with the DoD-Veterans Affairs clinical practice guideline for type 2 diabetes and the SDSCA survey instrument.

Since different PAM levels require different strategies, we addressed varying needs through a combination of applied constructs. Specifically, level 1 messages must address the emotional state of feeling overwhelmed and passive with an emphasis on the importance of taking action. To address the needs of PAM level 1 patients, we use constructs from social networks and social support theory [61], specifically that of emotional support that emphasizes expressions of empathy and caring. We encourage a sense of hope by expressing the belief and expectation that the message recipient can change his or her situation and overcome difficulties. Constructs from the transtheoretical model [62] such as visioning, dramatic relief, self-reevaluation, and environmental reevaluation also guided level 1 message development.

PAM level 2 messages build knowledge and self-efficacy to engage in a behavior and focus on ways to take small steps that don't require much in-depth knowledge. Self-efficacy and the confidence a person feels about performing a particular activity was a primary construct used to develop these messages with a focus on one of the main strategies to build self-efficacy, that of taking small steps that are likely to result in performance accomplishment. Outcome expectations, or the anticipatory outcomes of a behavior, stated in ways that would likely appeal to the expectancies or values a person places on the outcome, was also an important construct [63].

PAM level 3 messages assume some knowledge and focus more on building self-management skills such as goal setting and self-monitoring. For messages in this level, we used transtheoretical model [62] constructs relevant to the preparation and action stages of behavior change.

PAM level 4 messages about staying the course and avoiding relapse when stressed were grounded in the transtheoretical model constructs guiding processes used in the maintenance stage of change. Also used in level 4 message development were strategies developed in a relapse prevention model [64] such as identifying high-risk situations for relapse and the development of specific coping strategies for those situations.

In phase 2 of our study, tailored behavioral messages will be sent to each intervention group participant, via the MHCE accessed through their mobile device, based on both senior research associate-initiated and algorithm-automated schedules and thresholds developed according to PAM level, SDSCA responses, and agreed-upon general rotation. Figure 2 offers examples. The senior research associates will use the MHCE backend portal control panel for manual rotational scheduling of messages to be delivered 3 days per week (typically Monday, Wednesday, and Friday) within the MHCE system. Participant responses to the SDSCA may trigger additional messaging if their clinical readings from biomedical devices exceed established safety thresholds.

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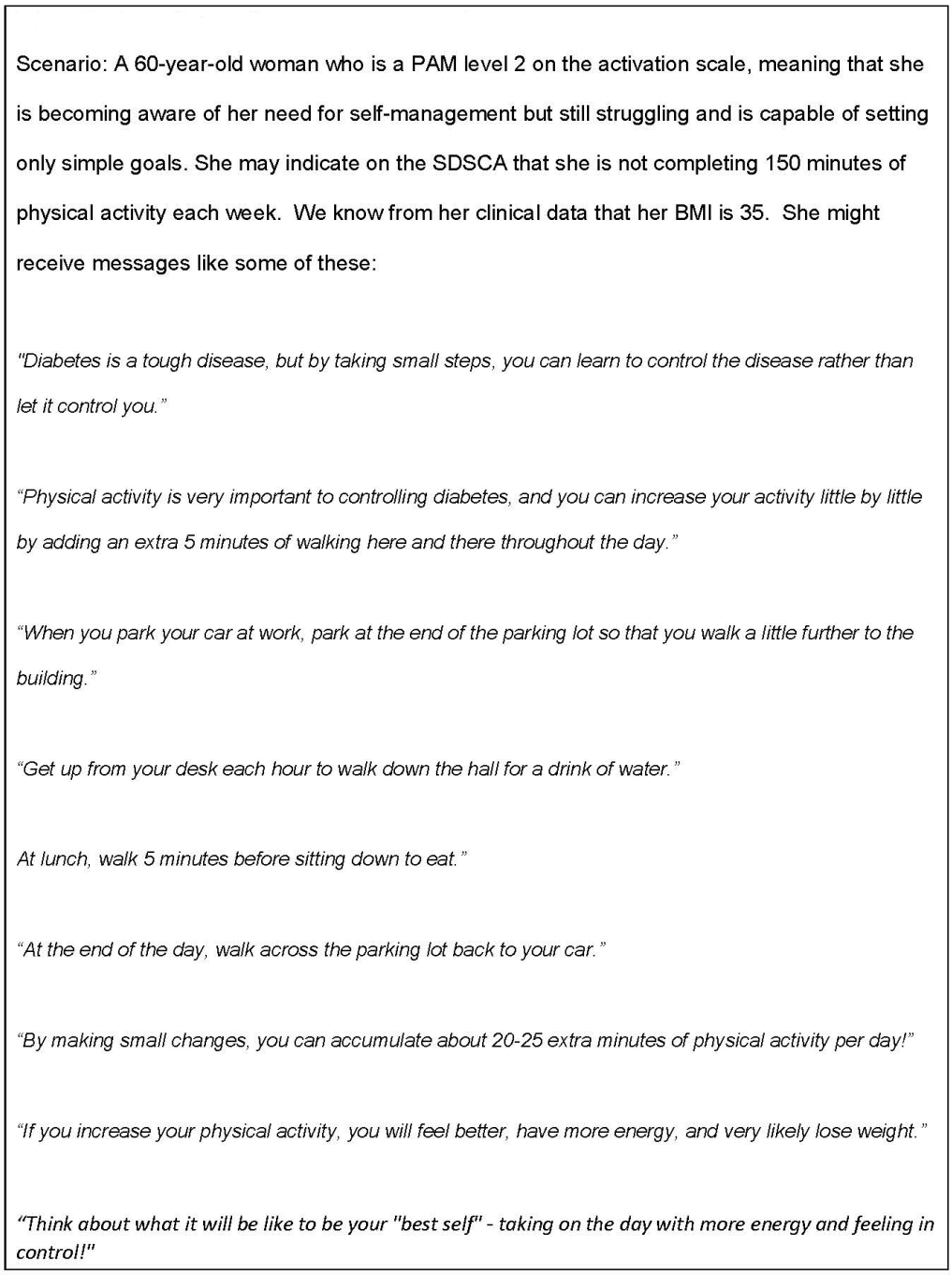
Figure 2. Example of tailored health messaging.



Phase 1 User-Centered Design Study Flow

In phase 1 we will evaluate and gain feedback from patients with diabetes regarding MHCE app navigation, use of external devices, ease of use, and satisfaction. We will collect baseline research participant data to include basic demographic data and clinical measures following verification of informed consent. One researcher-facilitator will lead individual participants through usability testing and the additional researcher-observer will document observations. During a facilitator-provided demonstration of the MHCE, the facilitator will ask each participant to concurrently navigate to each component of the MHCE system via a mini tablet device under their control. For each task, we will ask 3 open-ended questions to evaluate task-specific user satisfaction regarding the look and layout of the app, how the app functions, and any specific issues that are confusing. Next, the facilitator will give a brief demonstration of the external devices that will be used in the study: a blood pressure monitor, a glucometer, a digital precision weight scale, and a Fitbit Charge wireless activity and sleep wristband. For each device, we will ask participants to (1) manually upload data, (2) sync each device with the app, and (3) interpret graphs. While it would be preferable to observe the MHCE in the context of where the patient would actually use the system, financial limitations prohibit such expanded usability observation research.

Research staff will evaluate usability by applying definitions and usability evaluation metrics guided by the International Organization for Standardization's 9241-11 usability framework

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and mHealth usability research [65]. Specific metrics to evaluate usability are effectiveness, efficiency, and satisfaction. We will evaluate effectiveness via task completion and error coding. We will assess timed task completion as a task being completed with ease, being completed with minor mistakes, or not completed. Errors will be coded using a codebook developed by the phase 1 team. The observer will also note when users commit errors they cannot solve or commit errors that prevent further progress. We will use the Single Ease Question to evaluate informant satisfaction immediately after performing each task [66]. The System Usability Scale (SUS) will evaluate overall informant satisfaction with the MHCE [67].

We will also assess provider preferences in phase 1 using focus groups of clinicians and nurses recruited from the 2 study sites. Two trained qualitative researchers will facilitate the focus groups. We will take field notes during the focus groups and audio record each session to ensure accuracy of the field notes. The facilitators will use a semistructured interview guide to elicit clinician and nurse feedback about the MHCE. After briefly demonstrating the app, facilitators will ask 6 broad questions (with probes), developed by the phase 1 team in conjunction with study coinvestigators. These questions are designed to elicit feedback from participants regarding app design, alerts (general), wording of alerts, perceived usefulness to patients for promoting self-management, clinical usefulness and workflow, and backend portal data summaries. We will probe specific issues related to clinical usefulness of the MHCE in the context of the clinical workflow of the PCMH environment.

A 4-member team will complete a thematically organized data analysis of the clinician and nurse feedback using an inductive narrative approach [68-70]. We will begin with an analysis of field notes from 1 randomly selected provider and 1 nurse to create an initial codebook. We will expand the codebook as we continue to code field notes. The analysis team will divide the coding duties so that each transcript is coded by 2 independent coders [71]. The team will meet during the coding process to address consensus, update the coding structure, and revisit any previously coded field notes that need to be reviewed again based on these updates. Codes will be applied to the transcripts using Atlas.ti software version 7.5.10. Codes drawn from the interview guide will serve as the organizing framework for analysis. As new themes emerge, we will expand the narrative.

Phase 2 Controlled Study: Patient Enrollment and Study Flow

For phase 2 we will recruit 240 patients (120 per site), with half assigned as a control group. Eligible patients will be first assigned to 4 strata according to their PAM score. After all patients are identified and assigned into the strata, simple randomizations will be performed within each stratum to assign patients to either the MHCE or usual care groups. Patients will be randomly allocated to either the control or the intervention group based on their PAM scores.

We will modify the MHCE system between phase 1 and phase 2 research, incorporating phase 1 observations and optimizing system usability at the patient level. We will collect baseline research participant data, including basic demographic data and clinical measures, following verification of informed consent.

MHCE Intervention Versus Usual Care

Patients in both the intervention and usual care (control) groups will receive a device package as outlined in Textbox 1. These devices will collect and record biometric data. All patients will be trained in using biomedical devices and peripheral equipment.

Textbox 1. Patient device package (intervention and control groups).

- Activity monitor (Bluetooth and cloud enabled)
- Scale (Bluetooth enabled)
- Blood pressure cuff (Bluetooth enabled)
- Glucometer (Bluetooth enabled)

For the patient groups allocated to the intervention, their devices will be mapped to the MHCE system accessible from the patients' mobile phone or an iPad mini tablet device. Data from their biomedical devices will be visually presented in the MHCE with trend and scalable options (Figure 3).

Safety algorithms will be mapped to these clinical data to alert the patient and, depending on the measure, the clinical team when readings exceed established thresholds. The intervention groups will also have full access to and will receive the tailored behavioral messaging outlined above. At time of study enrollment, we will provide a tablet device to patients who are fully eligible to participate, are allocated to the intervention group, but do not have a mobile phone (with iOS or Android operating system).

In both the intervention and control groups, the patients' clinician and PCMH support team will be notified of the patients' enrollment in the study. The intervention patients will be encouraged to regularly use the MHCE system as a tool to improve their diabetes self-care.

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Figure 3. Example of visualization of patient data. BP: blood pressure.

Initial Outcome Measures for Patient Component

Primary outcome measures are PAM scores. Secondary outcome measures in the study are (1) SDSCA responses, (2) clinical measures (Textbox 2), (3) comorbid conditions (eg, uncontrolled plasma glucose, hypertension, hyperlipidemia, stoke, eye disease, coronary heart disease), (4) SUS survey scores, (5) MHCE usage statistics, and (6) health services utilization measures.

Textbox 2. Clinical measures in phase 2.

- Glycated hemoglobin (HbA_{1c})
- Low-density lipoprotein
- High-density lipoprotein
- Height and weight
- Abdominal circumference
- Systolic blood pressure
- Diastolic blood pressure

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Patient Activation Measure Instrument

The self-reported PAM survey is associated with self-management behaviors, medication adherence, patient satisfaction, and quality of life [55,72]. Within a diabetes-specific population, PAM is not related to knowledge regarding HbA_{1c} (the standard measure of average blood glucose level [73]), but is associated with better glycemic control [74]. Interventions, including educational programs [31], care coaching [32], and motivational interviewing [33], have been attempted to improve this activation with varied success. Specifically, patient activation can be increased with targeted, patient-centered, repeated messaging [19]. The PAM is a valid, reliable, unidimensional, probabilistic Guttman-like scale that was validated over a decade ago [21] and is a standard tool to measure patient activation. We will administer the PAM at screening visits in phases 1 and 2, and electronically every 3 months during phase 2 for both the intervention and control groups. Figure 4 outlies the 4 PAM levels.

Figure 4. The 4 levels within the Patient Activation Measure (PAM) survey.

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Summary of Diabetes Self-Care Activities Instrument

The SDSCA instrument is a brief self-report instrument for measuring levels of self-management across different components of the diabetes regimen [56]. The SDSCA includes 11 core items associated with diabetes self-care. The SDSCA has been successfully used in numerous diabetes studies both within and outside the United States [56,75-78]. The SDSCA has been validated and is considered a standard instrument in diabetes care for measuring self-care activities, with its validation and reliability published nearly two decades ago [56]. We will administer the SDSCA at the intake visit for phase 2, and electronically every 2 weeks during phase 2 for both the intervention and control groups.

Clinical Measures

We will collect clinical measures (Textbox 2) from patients at intake during phase 1 research. We will collect and compare changes in patient clinical measures for both groups in phase 2 at 3 points: intake, midpoint (month 6), and conclusion (month 12). For patients assigned to the MHCE intervention group, the MHCE system will also record weight, systolic blood pressure, diastolic blood pressure, and blood glucose values to the MHCE module on a regular basis via Wi-Fi or Bluetooth-enabled peripheral equipment.

Clinician Support for Patient Activation Measure

The Clinician Support for Patient Activation Measure (CS-PAM) instrument measures clinician beliefs about patient self-management behavior. The CS-PAM has been a valid and reliable instrument in use since 2010 [25]. The CS-PAM score indicates an individual clinician's overall level of endorsement or belief about the importance of patient self-management, as well as beliefs about the importance of specific patient competency categories [25].

In phase 2, we will measure clinician support for patient self-management by the CS-PAM. PCMH clinicians (ie, physicians, nurse practitioners, and physician assistants) in this study will take the CS-PAM at 3 points in the study: beginning, midpoint (month 6), and conclusion (month 12).

System Usability Scale Survey

The SUS survey is a 10-item Likert-like scaled survey used to convey a subjective assessment of system usability. The instrument was developed over 15 years ago and is used to measure the usability of websites. The SUS was validated on several occasions, with perhaps the largest validation study (including 10 years' worth of data) conducted in 2008 [79]. In this study we will substitute the term "MHCE system" for the term "website" in the instrument. We will conduct the SUS survey at the conclusion of the encounter for phase 1 patients, and at midpoint (months 5-6) and study conclusion (months 11-12) for phase 2 patients in the intervention group.

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MHCE Usage Statistics

Our technology enablement partners will embed counters (invisible to patients) that track usage of MHCE components. These counters will export usage data to our research analysis database. Summary statistics and trends will be analyzed with comparison.

Comorbid Conditions

We will assess and document comorbid conditions (eg, hypertension, hyperlipidemia) among both the control and intervention groups during prescreening of eligibility, at intake, at study midpoint, and at study conclusion. While not primary outcome measures, any change over time and whether the number and type of comorbid conditions influence patient use of MHCE will be assessed.

Data Analysis Strategy

We will conduct the primary analyses for phase 2 using an intent-to-treat approach. Study participants will be retained in their original assignment groups after the random allocation in the analysis. Achievement of randomization will be evaluated through the comparison of baseline key variables between the MHCE intervention group and the control group. We will also compare baseline key characteristics between eligible patients who participate in the study and those who do not participate to examine the potential for bias.

To test hypotheses 2 and 3, that patients who participate in MHCE will have higher PAM, SDSCA, and SUS scores and improved selected clinical outcomes and comorbid conditions than their counterparts in usual care, we will use multivariate regression models (logistic regression if the outcome is a binary variable and linear regression if the outcome is a continuous variable) with the intervention assignment as the primary independent variable. Stratified analyses will be conducted (eg, sex, race, and initial PAM score).

The primary comparison will be outcomes at 12 months. Additional analyses will use longitudinal analysis models using a generalized estimating equation, which will include outcomes at both 6 and 12 months.

To test hypothesis 4, that patients who engage at a higher rate with the interactive and tailored mobile technology in MHCE will realize greater improvement in clinical measures (eg, HbA_{1c} values; Textbox 2), we will use multivariate linear regression models. Clinical outcomes will be the dependent variables and will be tested separately. The main independent variable will be MHCE usage. We will examine the association between the dependent variable and MHCE usage by using the generalized estimate equation with adjustment of potential confounders (eg, age, sex, race, duration of disease, use or nonuse of insulin).

Trial Status

At the time of publication, we have completed phase 1 data collection. Formal analysis of phase 1 data has not been completed. Institutional review board approval (study and site implementation) has been obtained and phase 1 research commenced in late fall 2016.

Results

The hypotheses of the study suggest that patients can, and will, improve their activation in chronic care self-management. Improved activation should translate into improved diabetes self-care. While not powered in this study, improved self-management activities should lead to fewer emergency situations (and trips to the emergency department), weight loss (in many cases), improved blood pressure, and improved clinical measures. Cumulatively, the gains should translate into improved quality of life if our hypotheses are supported.

This study has been approved by the institutional review boards of Clemson University (protocol #IRB2015-234) and the Madigan Army Medical Center (representing both DoD sites; reference #216073). Study personnel will follow protocol with all informed consent mandates directed by the institutional review boards; informed consent in this study includes both patients and clinicians or key clinical staff. This trial was registered with ClinicalTrials.gov (NCT02949037) on October 31, 2016.

Discussion

Expected benefits of this research and development effort to the scientific community and health care services include improved understanding of how to advance 3 joint PCMH principles (ie, better coordination of care, improved quality and safety, and enhanced access to care) through the use of mobile technology and improved understanding of how to include mHealth technology in the clinical workflow of the PCMH health services model, as well as improved understanding of how to use mHealth technology to activate patients with a diagnosis of type 2 diabetes in disease self-management behaviors. We also expect to improve understanding of how patient complexity and degree of “sickness” may influence patient use or nonuse of mHealth technologies in self-management of their disease, and to explore how to map patient-entered biomedical data onto clinical documentation and a decision-support platform useful in chronic care management.

Our study design is not immune from potential threats to validity. Patients allocated to the control arm will be issued the same peripheral devices as the intervention group and, while they may not achieve the same degree of activation, they may realize improvement if they use the equipment being issued to them. Though this behavioral mechanism could benefit patients in the control group, a strong activation change in the control arm could conceal the behavioral benefit of our intervention when we compare patient behavior from the 2 arms.

We are aware that we did not conduct a power calculation for sample size, since this project was funded as a feasibility study, not a randomized controlled trial. Thus, sample size estimates are neither required nor appropriate. We additionally recognize that a formal randomized controlled trial would be preferred to our current design. A follow-on randomized controlled trial is our goal once we have collected sufficient data and have a better understanding of how patients will use this chronic care health

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information technology system. At that point we will legitimately be able to predict the intervention effect and properly power the study.

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Federal disclaimer: The views expressed are those of the authors and do not reflect the official policy of the Department of the Army, the Department of the Air Force, the Department of Defense, or the US federal government.

Authors' Contributions

RG initially conceptualized the study, and both RG and LS wrote the initial draft of the manuscript. PC, EAS, RG, WWS, KWE, MH, and JBM assisted in the setting narrative, enrollment strategies, and institutional review board-related issues. The technical aspects of the intervention and MHCE description were authored by JRL and RG. The biostatistics and data analysis strategy were developed by LC and KT. The patient activation and behavioral messaging component, including examples, was developed by CJD, JEW, SFG, and KOJ. The user-centered design component was researched and authored by JEW and SFG. The outcome measures component was conceptualized and authored by PC, EAS, KT, LS, CJD, JEW, LC, JBM, MH, WWS, and KWE. The clinical components, including inclusion and exclusion criteria, were developed by PC, EAS, CD, WWS, JBM, MH, KWE, and RG. The MHS review and component were authored by JBM, MH, KWE, and RG. All authors read, contributed to, critically reviewed, and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CS-PAM: Clinician Support Patient Activation Measure
DoD: Department of Defense
HbA1c: glycated hemoglobin
MHCE: Mobile Health Care Environment
MHS: Military Health System
PAM: Patient Activation Measure
PCMH: patient-centered medical home
PHR: personal health record
SDSCA: Summary of Diabetes Self-Care Activities
SMS: short message service
SUS: System Usability Scale

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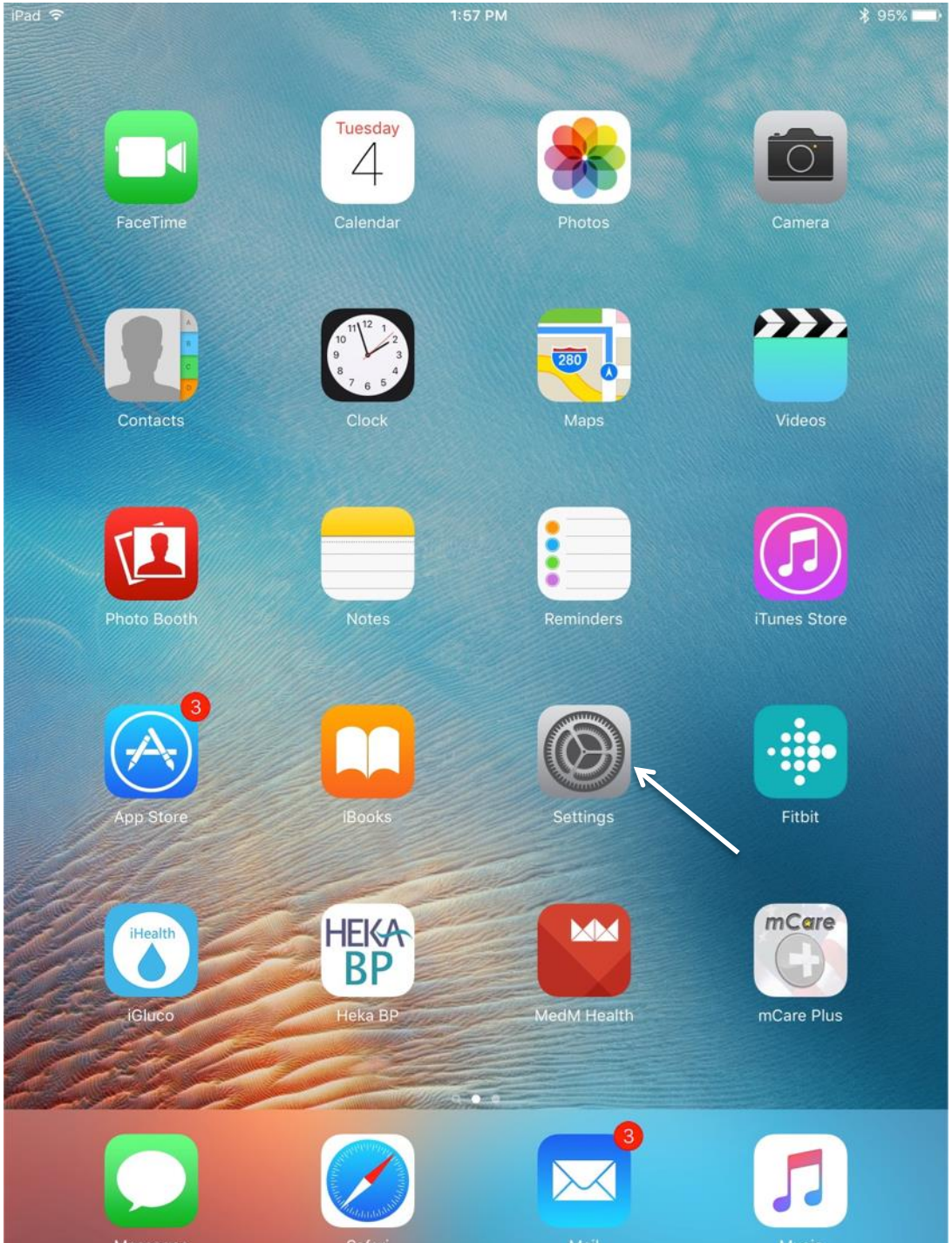
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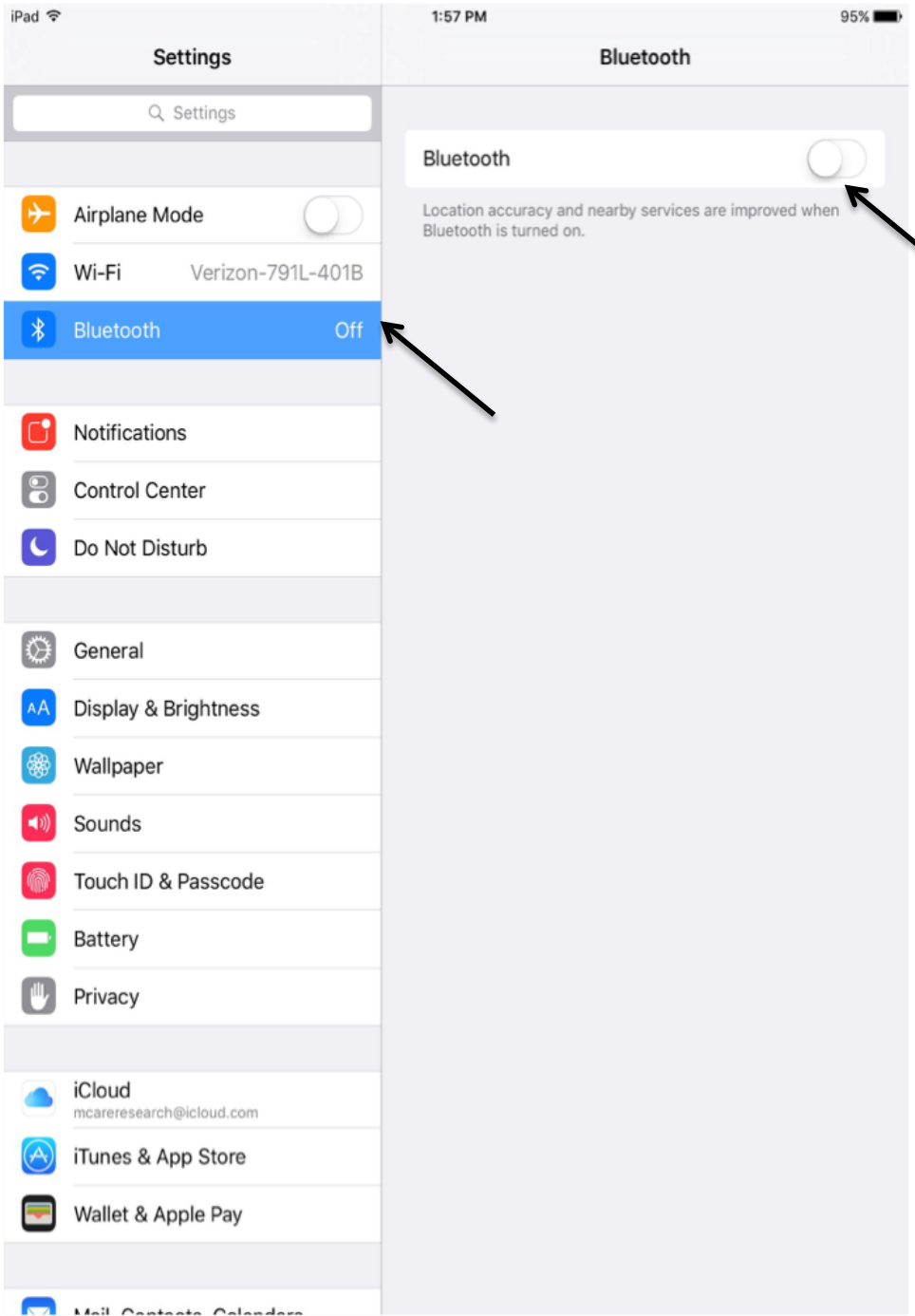
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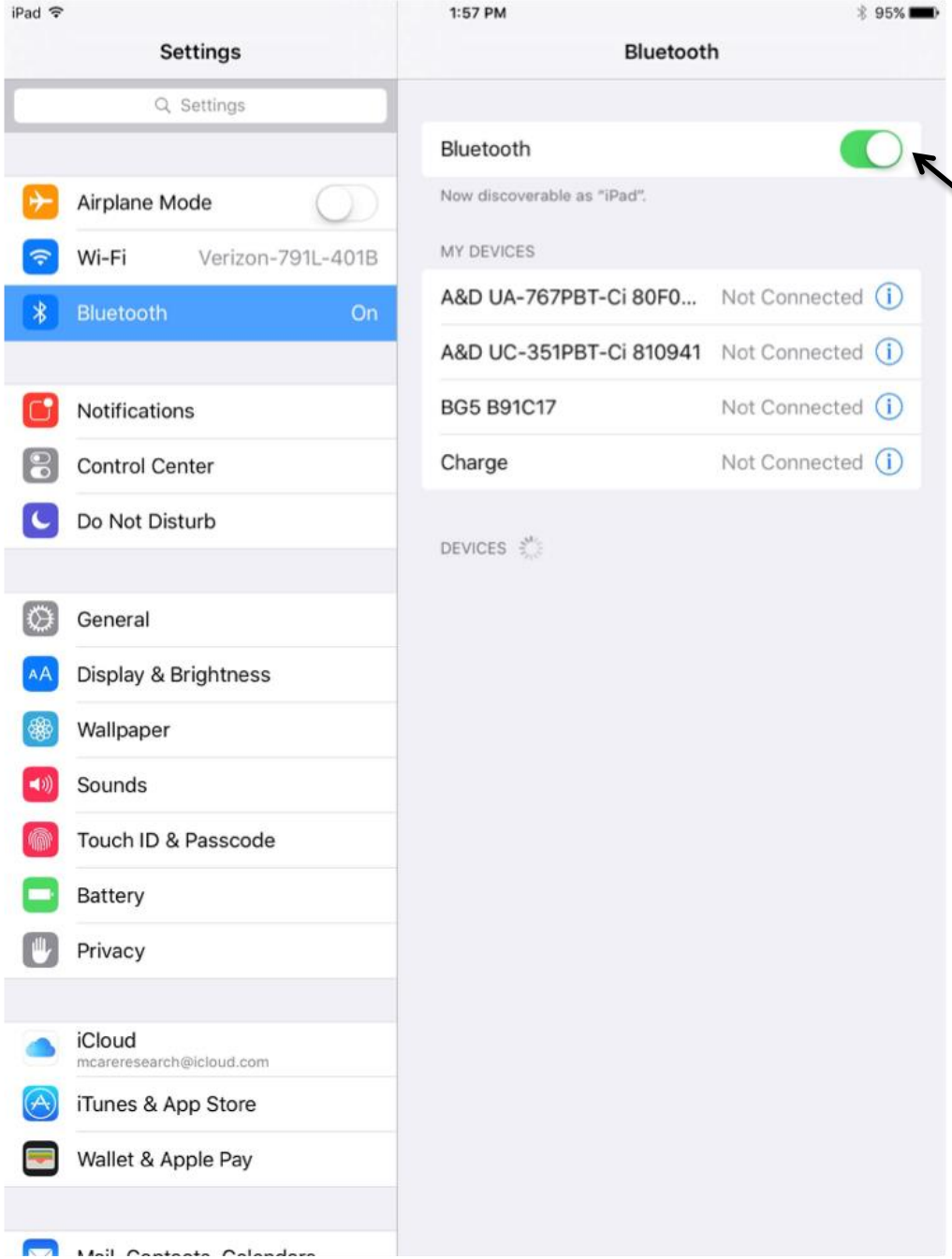
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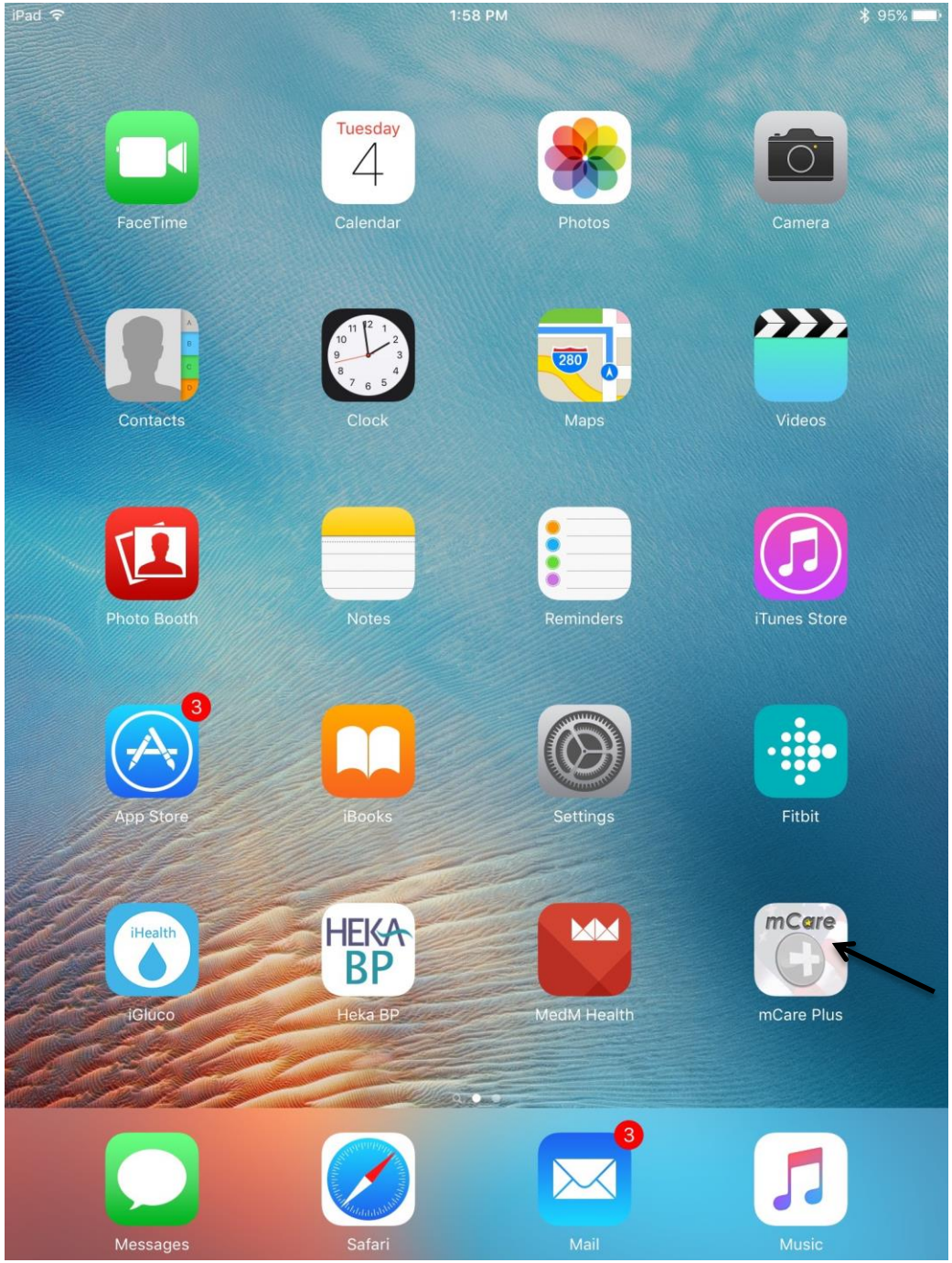
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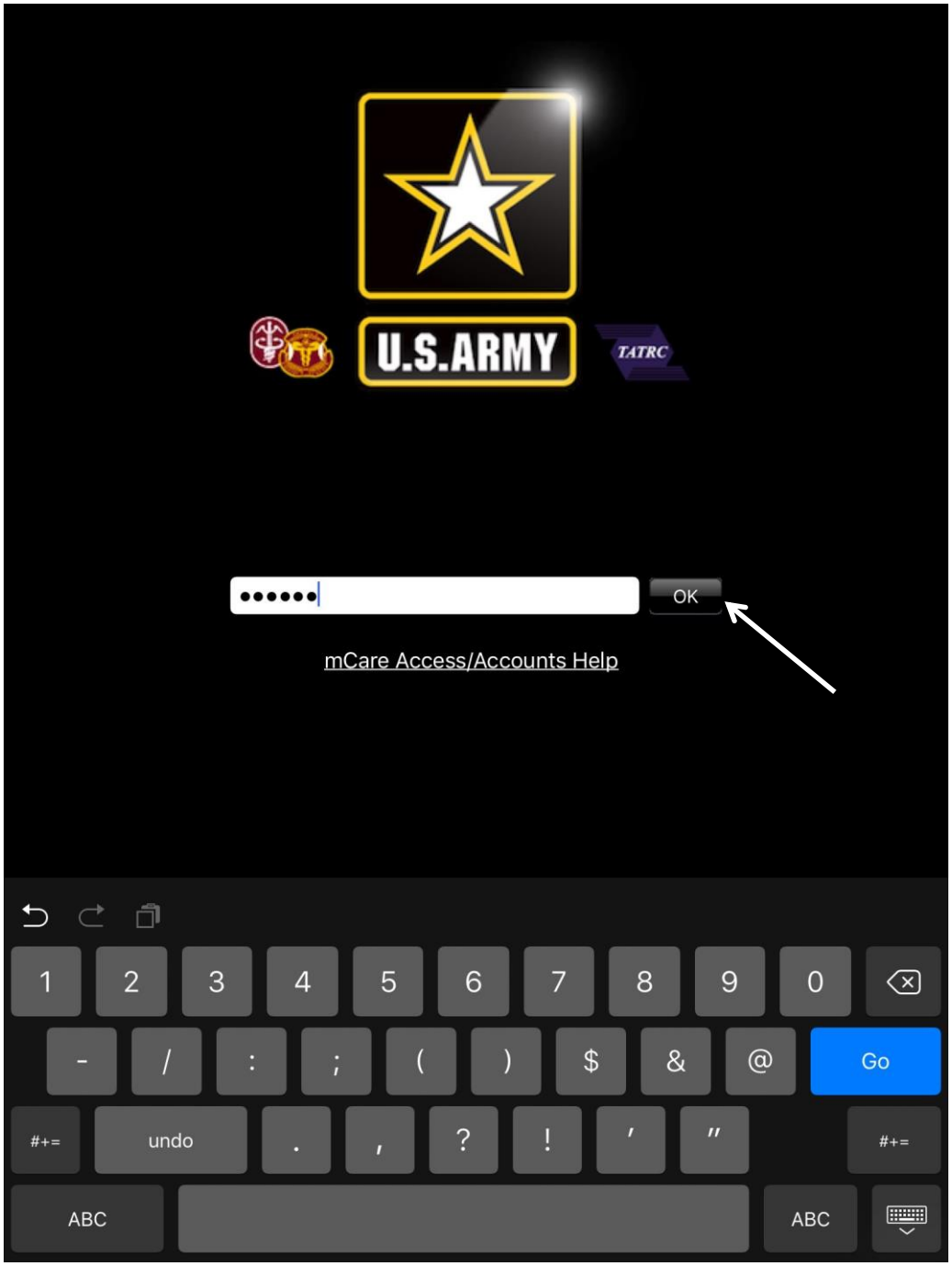
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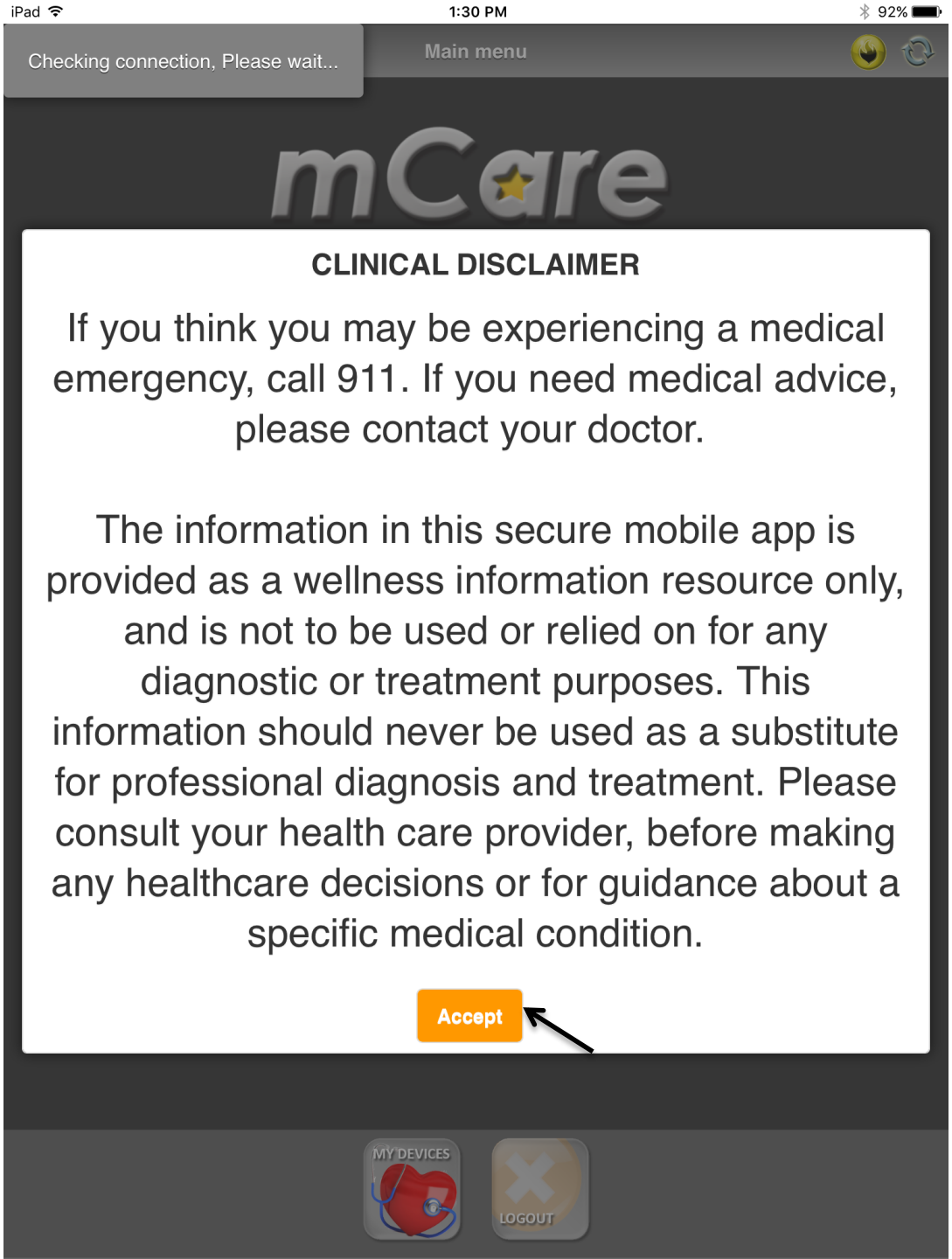
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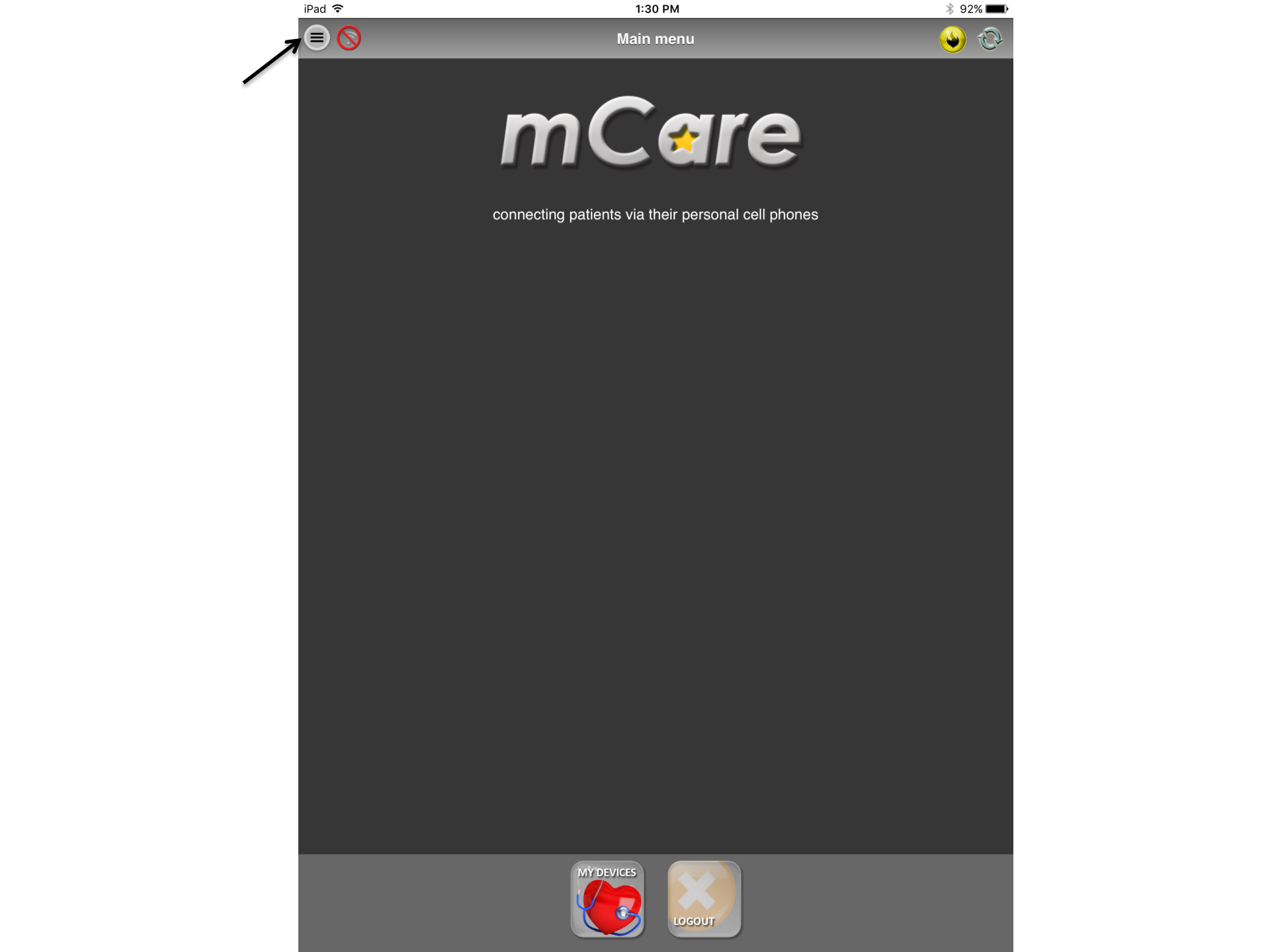
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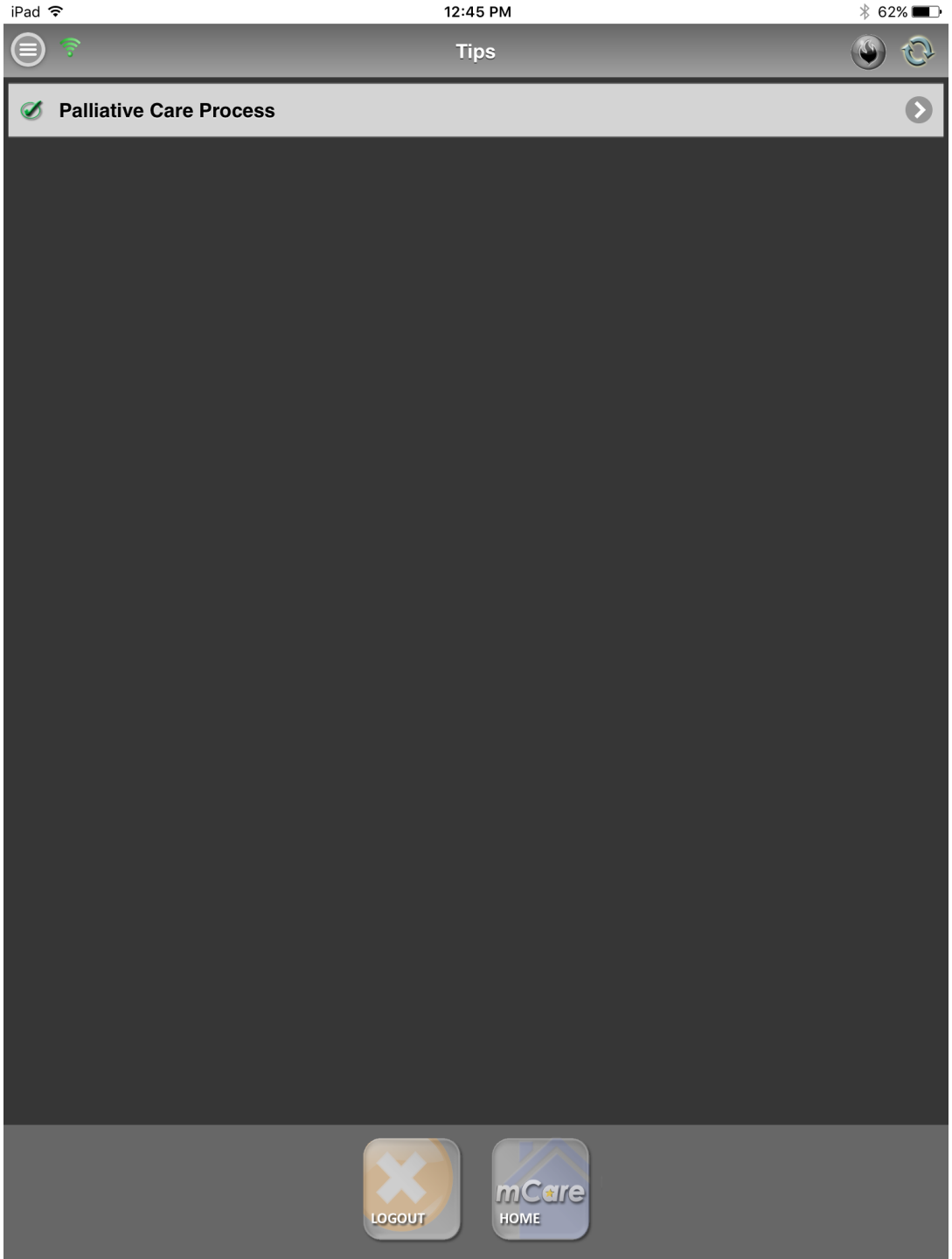
Announcements
Appointments
Reminders
Tips
Diabetes
Logout
menu
are
heir personal cell phones
LOGOUT

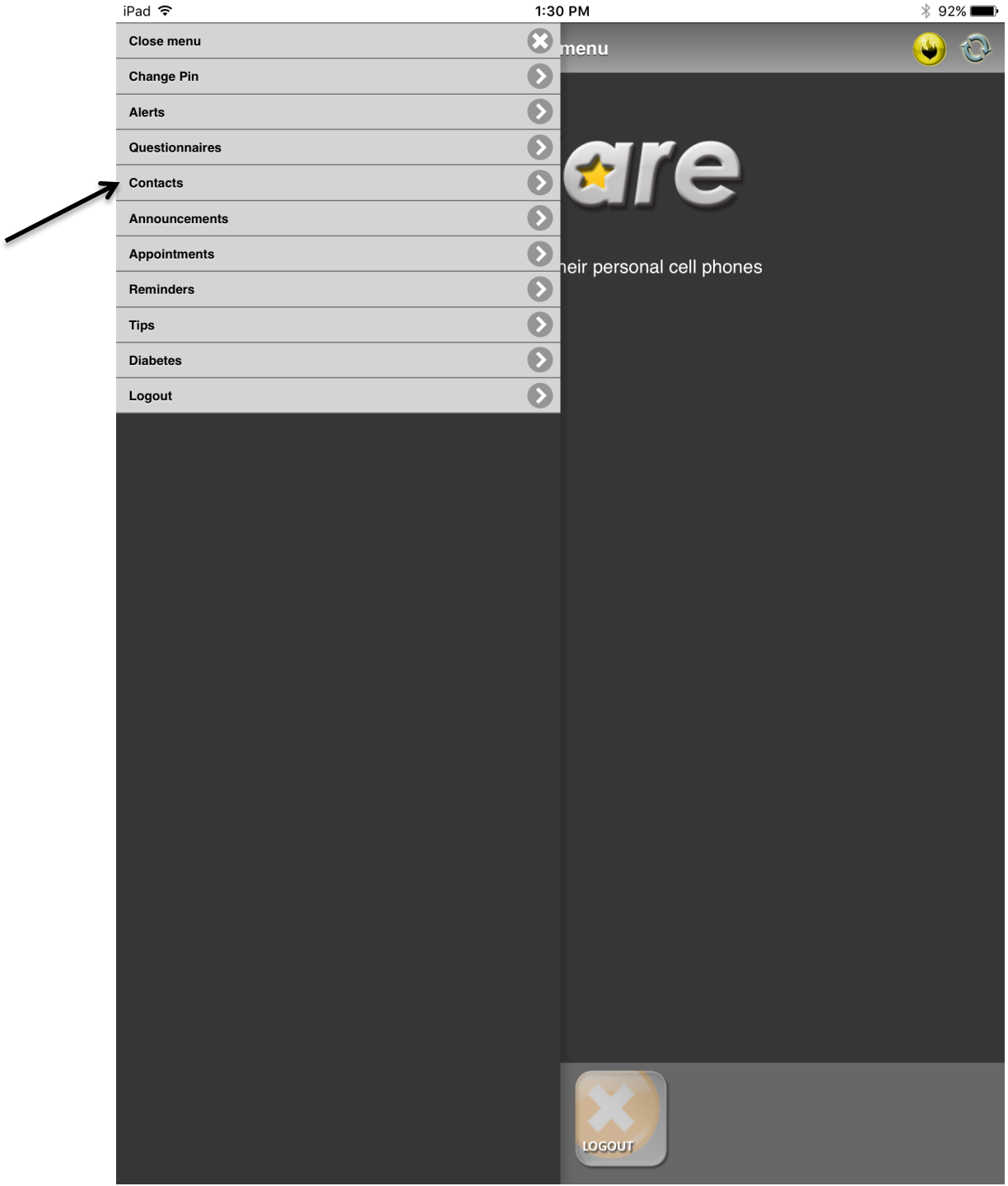

iPad
12:45 PM
62%
Tips
Palliative Care Process
LOGOUT
mCare
HOME

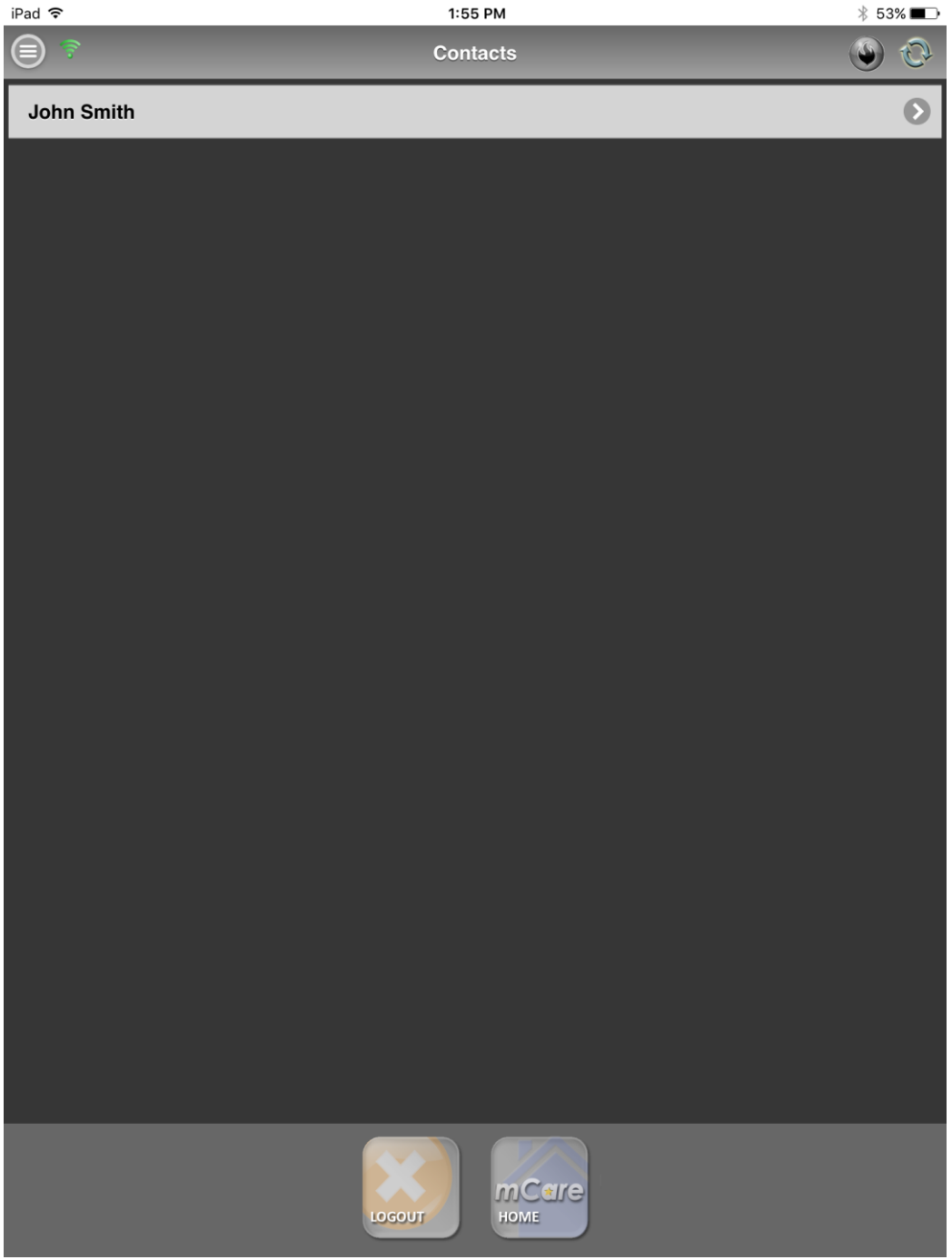
iPad 1:29 PM 82%

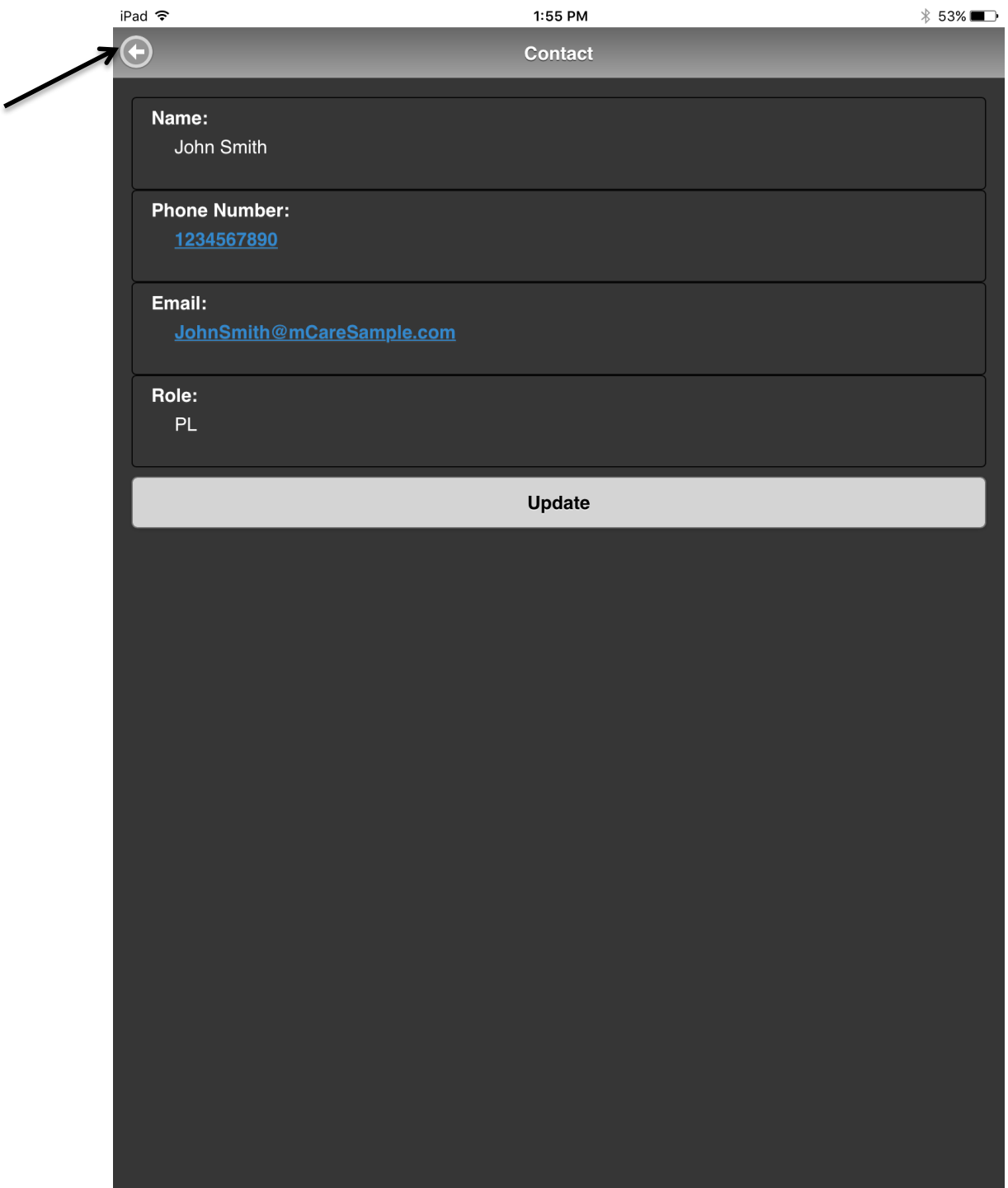
Health Tip

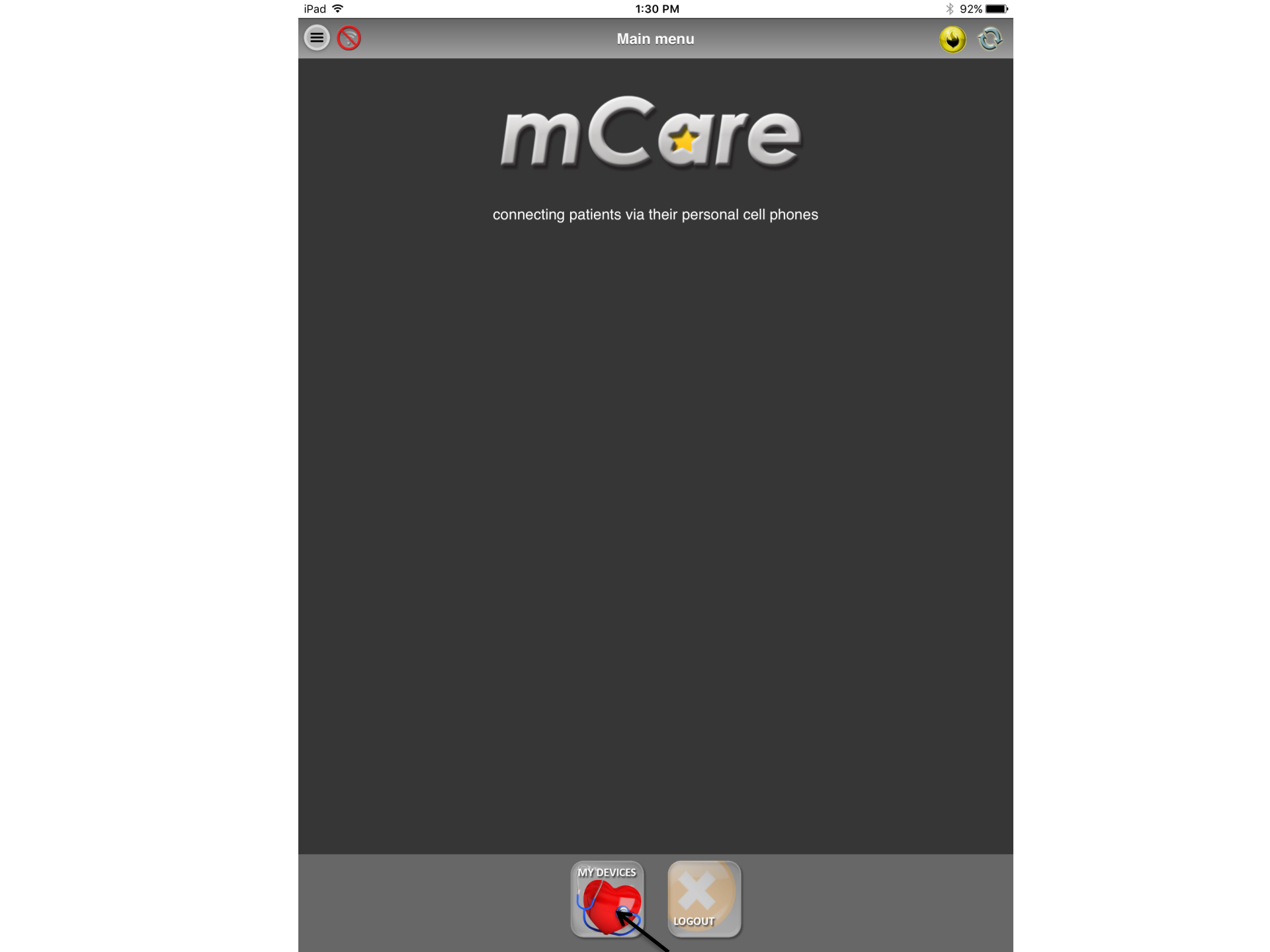
Palliative Care Process

Palliative Care is a comprehensive team approach that entails pain and symptom management, emotional support and counseling, and advanced care planning.

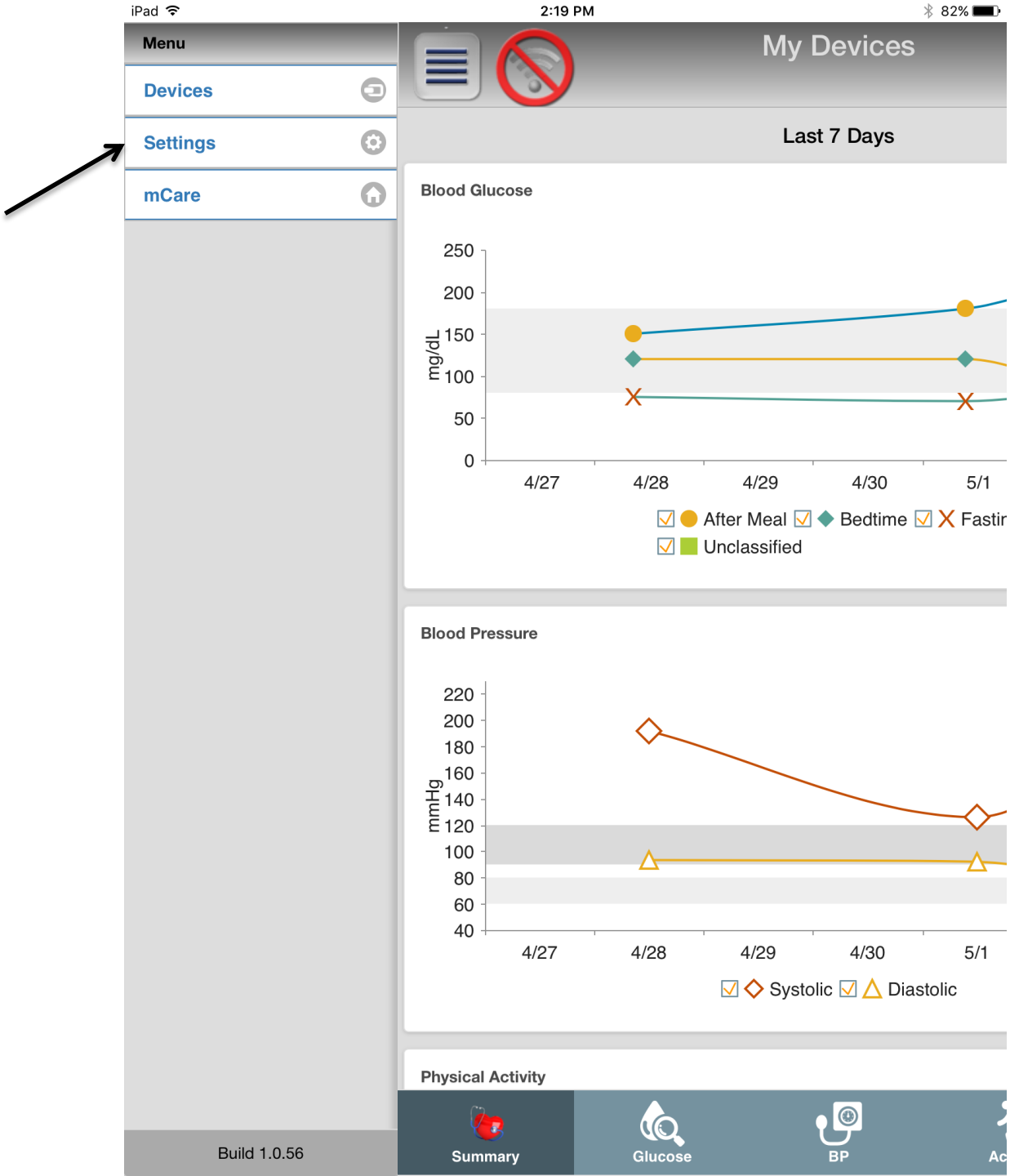

iPad
1:30 PM
92%
Close menu
Change Pin
Alerts
Questionnaires
Contacts
Announcements
Appointments
Reminders
Tips
Diabetes
Logout
menu
are
eir personal cell phones
LOGOUT


iPad
1:55 PM
53%
Contacts
John Smith
LOGOUT
mCare
HOME

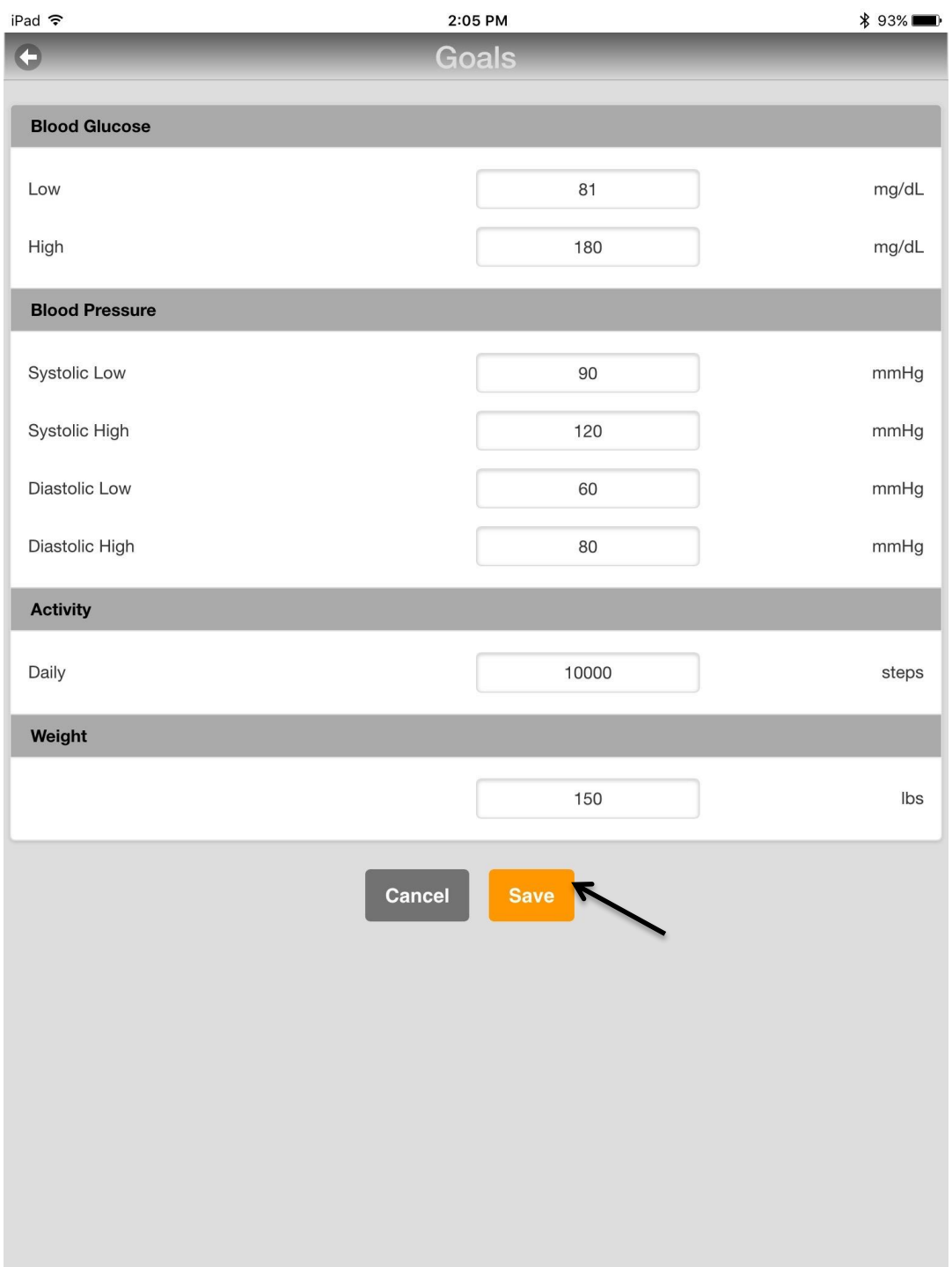

iPad
1:55 PM
53%
Contact
Name:
John Smith
Phone Number:
1234567890
Email:
JohnSmith@mCareSample.com
Role:
PL
Update


iPad
1:30 PM
92%
Main menu
mCare
connecting patients via their personal cell phones
MY DEVICES
LOGOUT

iPad
1:33 PM
91%
My Devices
Last 7 Days
Blood Glucose
250
200
150
100
50
0
mg/dL
4/27
4/28
4/29
4/30
5/1
5/2
5/3
After Meal
Bedtime
Fasting
Unclassified
Blood Pressure
220
200
180
160
140
120
100
80
60
40
mmHg
Systolic
Diastolic
Physical Activity
More
Summary
Glucose
BP
Activity
Weight
Menu
Announcements
Health Tips
Safety Alerts
Target Ranges


iPad
2:19 PM
82%
Menu
Devices
Settings
mCare
Build 1.0.56
My Devices
Last 7 Days
Blood Glucose
250
200
150
100
50
0
mg/dL
4/27
4/28
4/29
4/30
5/1
After Meal
Bedtime
Fastir
Unclassified
Blood Pressure
220
200
180
160
140
120
100
80
60
40
mmHg
4/27
4/28
4/29
4/30
5/1
Systolic
Diastolic
Physical Activity
Summary
Glucose
BP

iPad
2:05 PM
93%
Settings
Goals
Units


iPad
2:05 PM
93%
Goals
Blood Glucose
Low
81
mg/dL
High
180
mg/dL
Blood Pressure
Systolic Low
90
mmHg
Systolic High
120
mmHg
Diastolic Low
60
mmHg
Diastolic High
80
mmHg
Activity
Daily
10000
steps
Weight
150
lbs
Cancel
Save

iPad
1:33 PM
91%
My Devices
Last 7 Days
Blood Glucose
250
200
150
100
50
0
mg/dL
4/27
4/28
4/29
4/30
5/1
5/2
5/3
After Meal
Bedtime
Fasting
Unclassified
Blood Pressure
220
200
180
160
140
120
100
80
60
40
mmHg
4/27
4/28
4/29
4/30
5/1
5/2
5/3
Systolic
Diastolic
Physical Activity
More
Summary
Glucose
BP
Activity
Weight

Alerts

Health Tips

Weekly Measuring

When you are ready to make measuring glucose part of your daily life, make a plan for measuring your glucose regularly for a week. Write down your plan and be specific about when, where, and how you will measure your glucose.

Today

1:28 PM 500 After Meal

If your blood sugar is greater than 300 mg/dL, drink water, be active, and check your blood sugar before meals and at bedtime until it is less than 200.

If it does **NOT** go down, contact your doctor.

1:28 PM 500 After Meal

Contact your doctor if your blood sugar is **over** 250 mg/dL for 24 hours.

1:28 PM 500 After Meal

Contact your doctor if your blood sugar is **over** 250 mg/dL for 24 hours.

1:27 PM 200/110

IMPORTANT: If you have chest pain, shortness of breath, back pain, numbness/weakness, change in vision or difficulty speaking, call 911 immediately!

Otherwise, for systolic blood pressure **above** 181, wait ten minutes at rest and recheck. If your systolic reading (the top number) is still above 181 and you do not have any other symptoms, contact your doctor.

1:27 PM 200/110/110

If your pulse is greater than 100 beats per minute at REST, contact your healthcare provider.

1:18 PM

If you need assistance with your F[illegible]onitor, please contact your assigned mCare Research Associate or the mCare Help Desk staff for assistance.

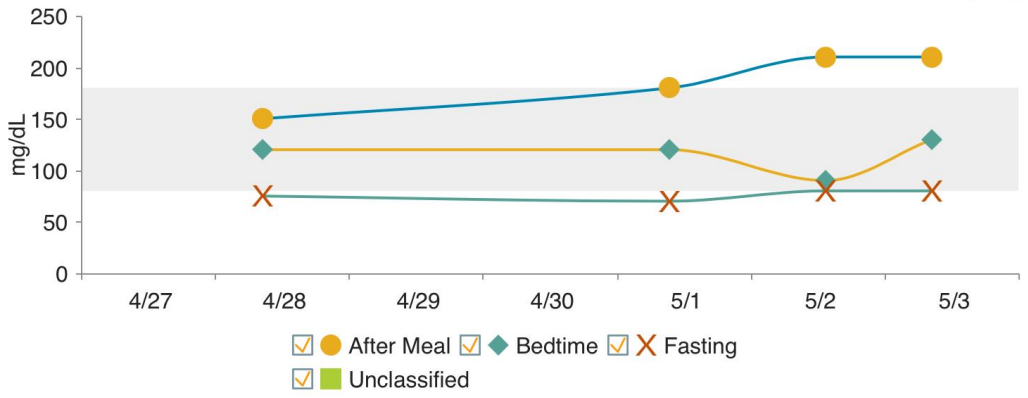
More

Your assigned points of contact can be found in the Contacts section.

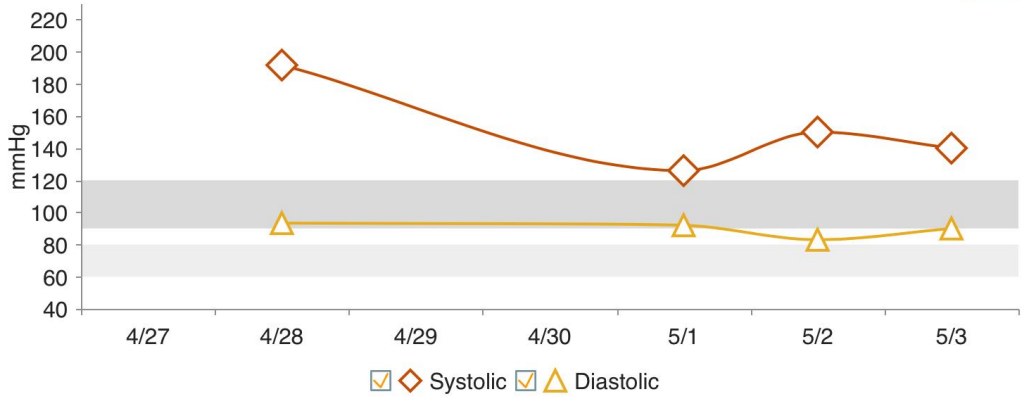
My Devices

Last 7 Days

Blood Glucose

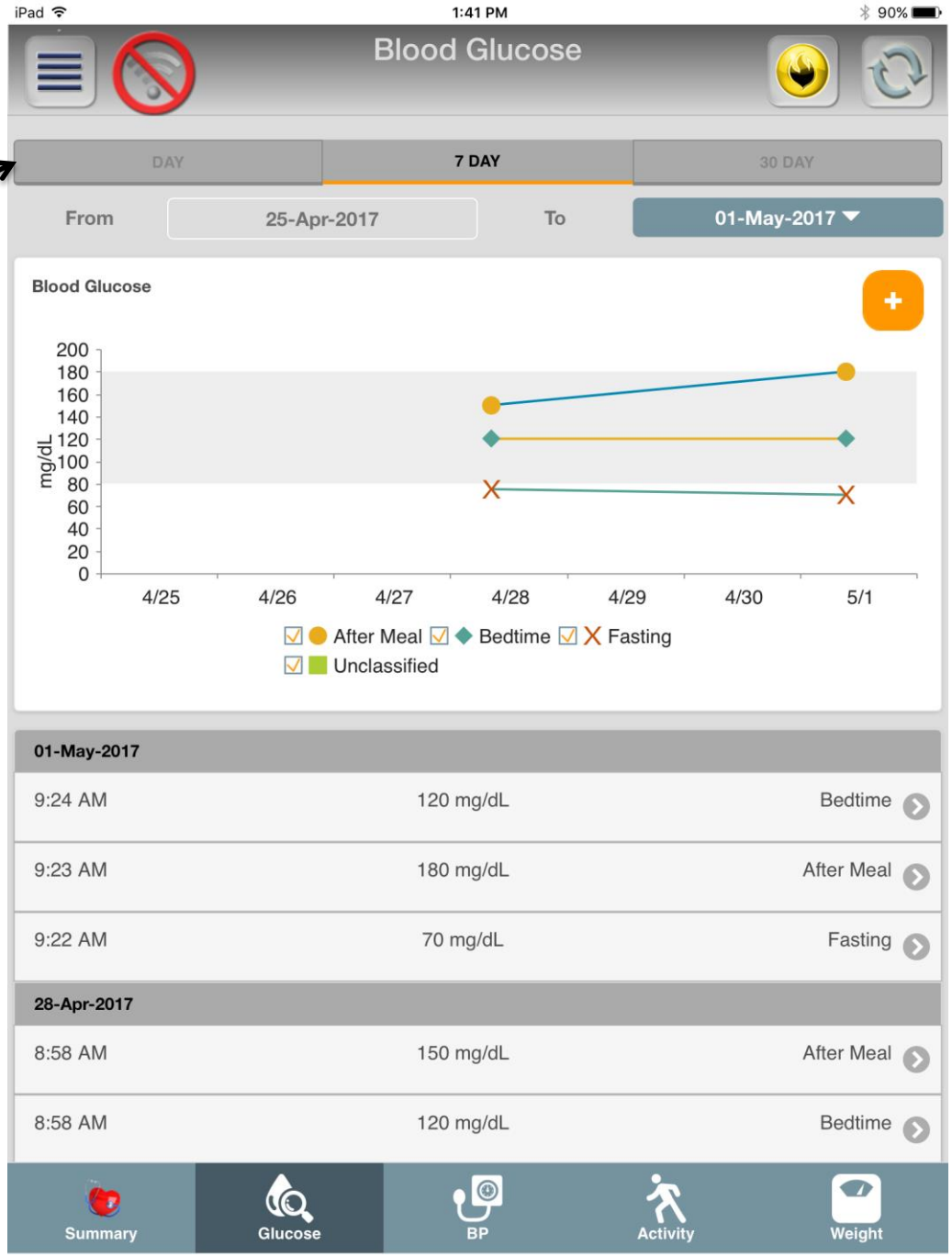


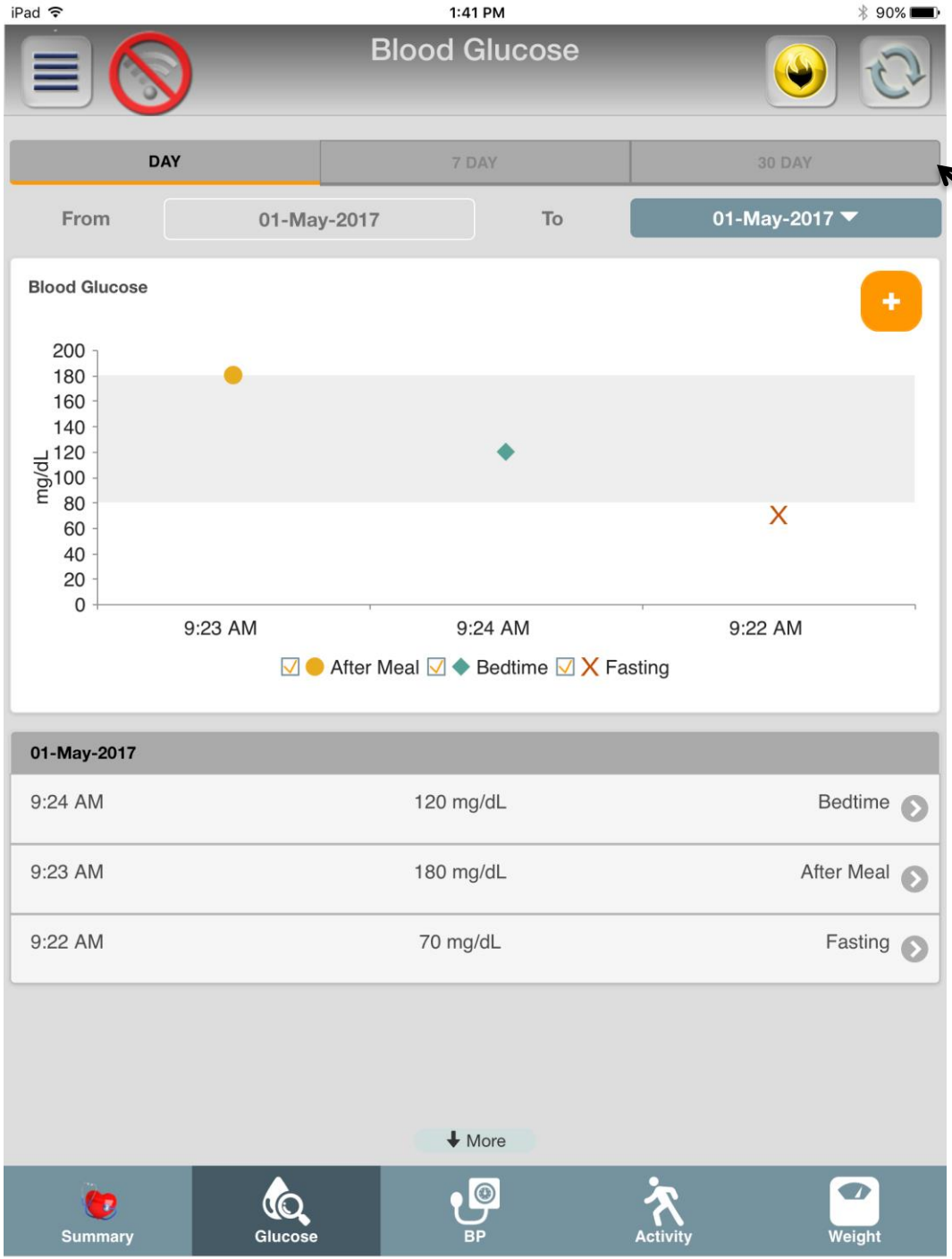
Blood Pressure

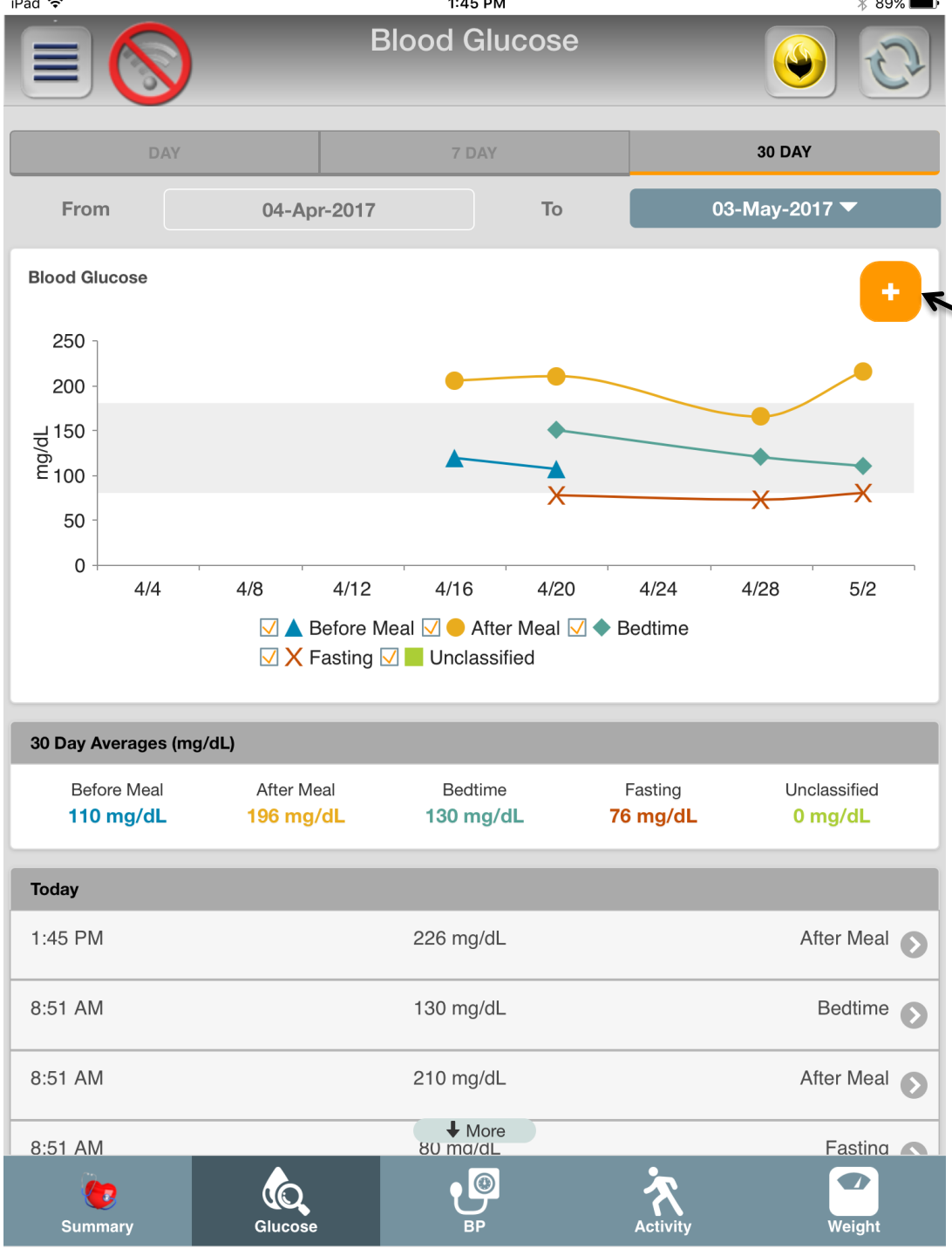


Physical Activity

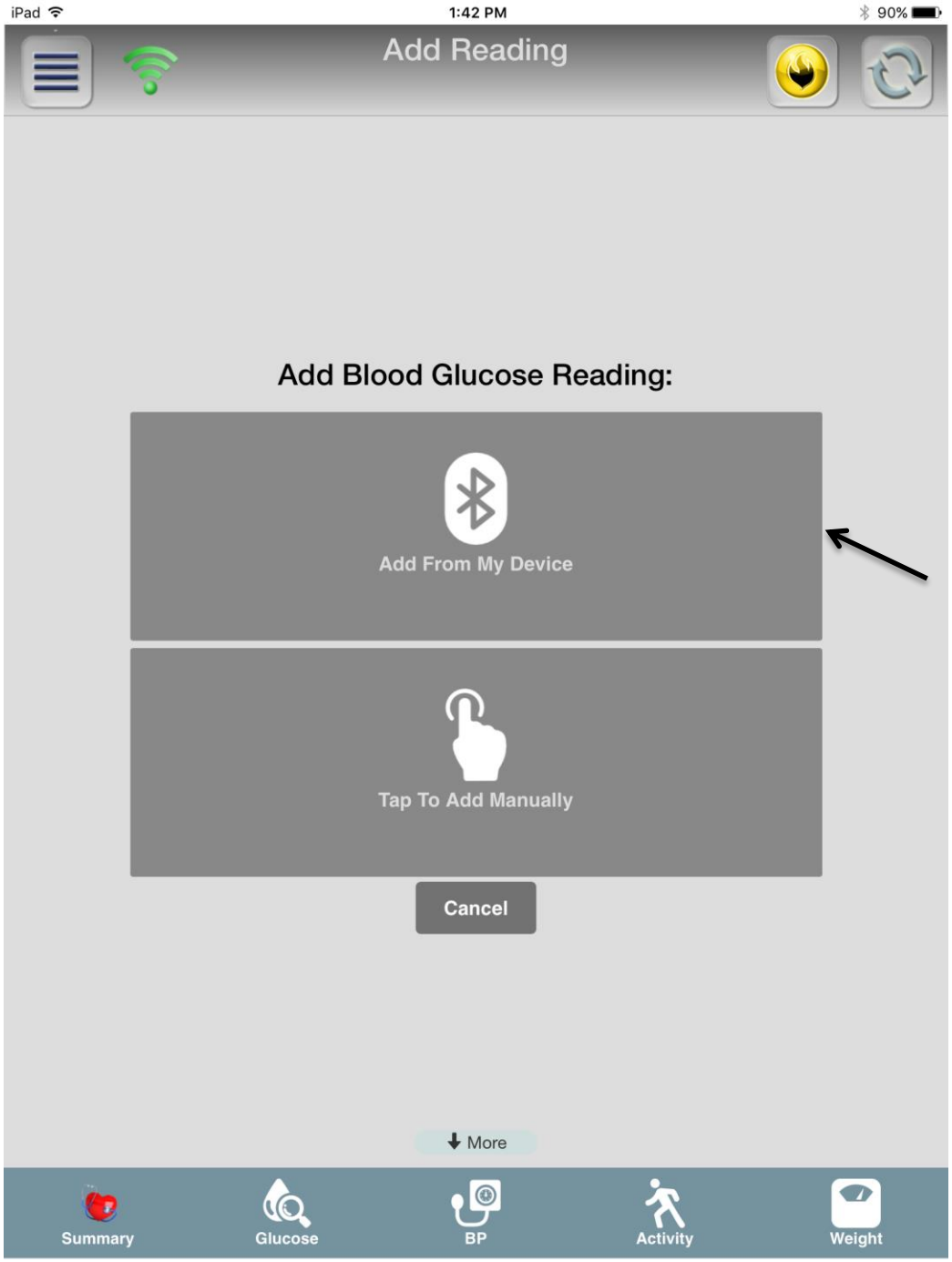
More


iPad
1:41 PM
90%
Blood Glucose
DAY
7 DAY
30 DAY
From
25-Apr-2017
To
01-May-2017
Blood Glucose
200
180
160
140
120
100
80
60
40
20
0
mg/dL
4/25
4/26
4/27
4/28
4/29
4/30
5/1
After Meal
Bedtime
Fasting
Unclassified
01-May-2017
9:24 AM
120 mg/dL
Bedtime
9:23 AM
180 mg/dL
After Meal
9:22 AM
70 mg/dL
Fasting
28-Apr-2017
8:58 AM
150 mg/dL
After Meal
8:58 AM
120 mg/dL
Bedtime
Summary
Glucose
BP
Activity
Weight


iPad
1:41 PM
90%
Blood Glucose
DAY
7 DAY
30 DAY
From
01-May-2017
To
01-May-2017
Blood Glucose
200
180
160
140
120
100
80
60
40
20
0
mg/dL
9:23 AM
9:24 AM
9:22 AM
After Meal
Bedtime
Fasting
01-May-2017
9:24 AM
120 mg/dL
Bedtime
9:23 AM
180 mg/dL
After Meal
9:22 AM
70 mg/dL
Fasting
More
Summary
Glucose
BP
Activity
Weight



Add new value option available on 30 day, 7 day, or day view.


iPad
1:42 PM
90%
Add Reading
Add Blood Glucose Reading:
Add From My Device
Tap To Add Manually
Cancel
More
Summary
Glucose
BP
Activity
Weight

iPad 2:39 PM 78%

Add Reading

Blood Glucose Reading

1 Please Select Type Of Reading

All Readings | Current Reading

2 Take Reading

Insert Strip

.....

Place Droplet of Blood on Strip

.....

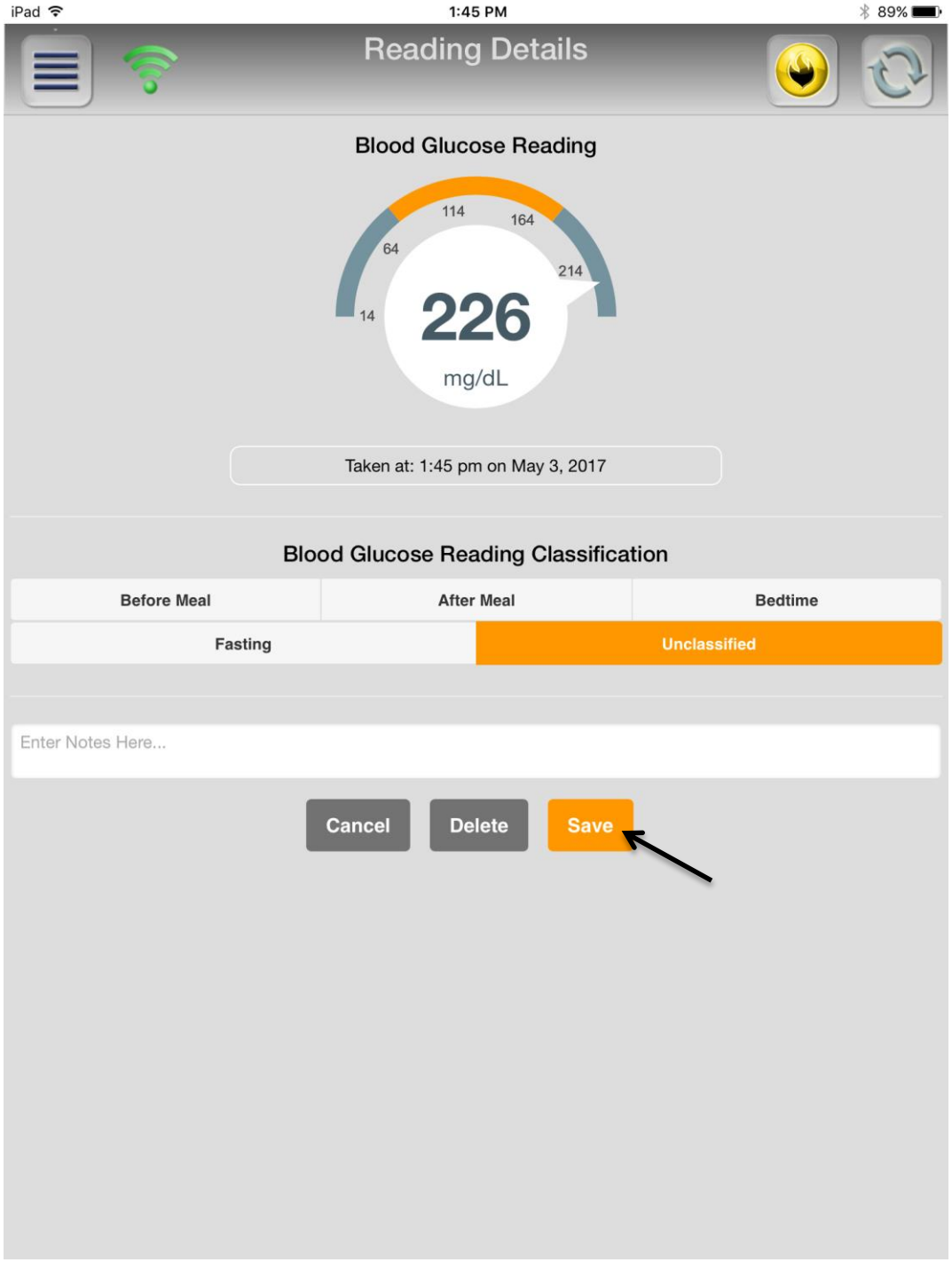
Eject Strip

3 Sync Reading

Add From My Device

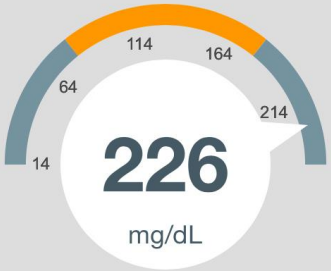
Manually Input

Cancel


iPad
1:45 PM
89%
Reading Details
Blood Glucose Reading
14
64
114
164
214
226
mg/dL
Taken at: 1:45 pm on May 3, 2017
Blood Glucose Reading Classification
Before Meal
After Meal
Bedtime
Fasting
Unclassified
Enter Notes Here...
Cancel
Delete
Save

Reading Details

Blood Glucose Reading



Taken at: 1:45 pm on May 3, 2017

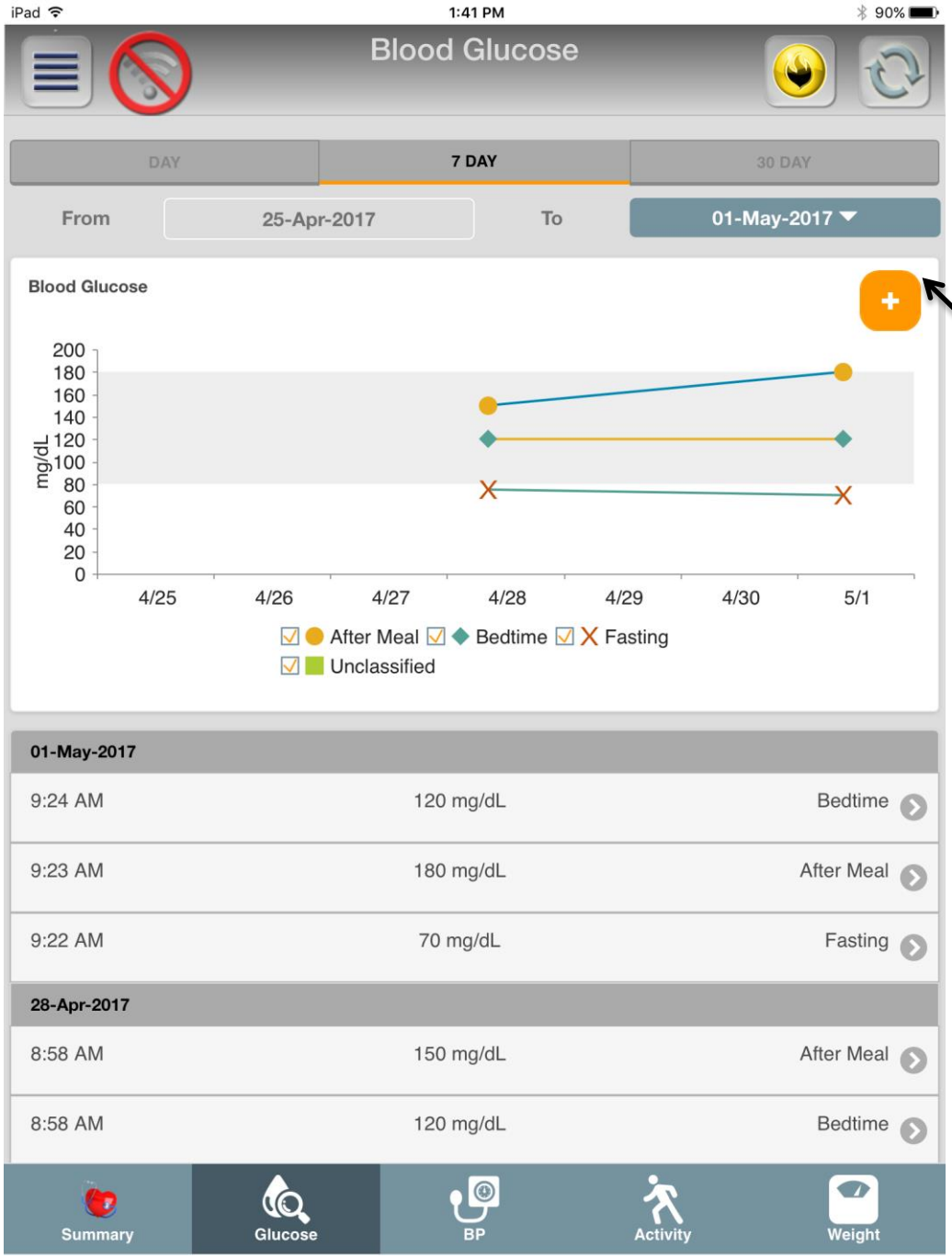
Blood Glucose Reading Classification

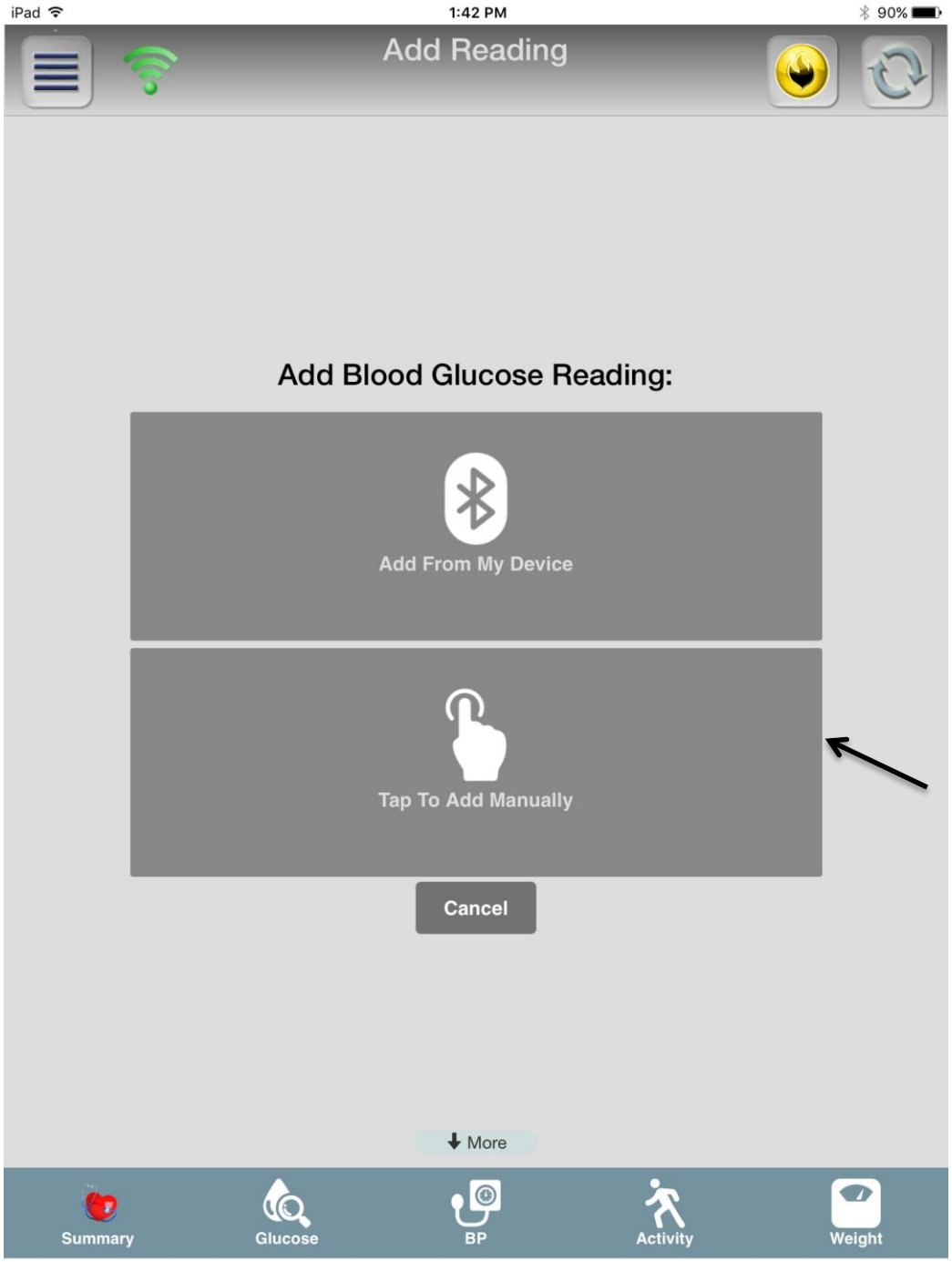
Before Meal	After Meal	Bedtime

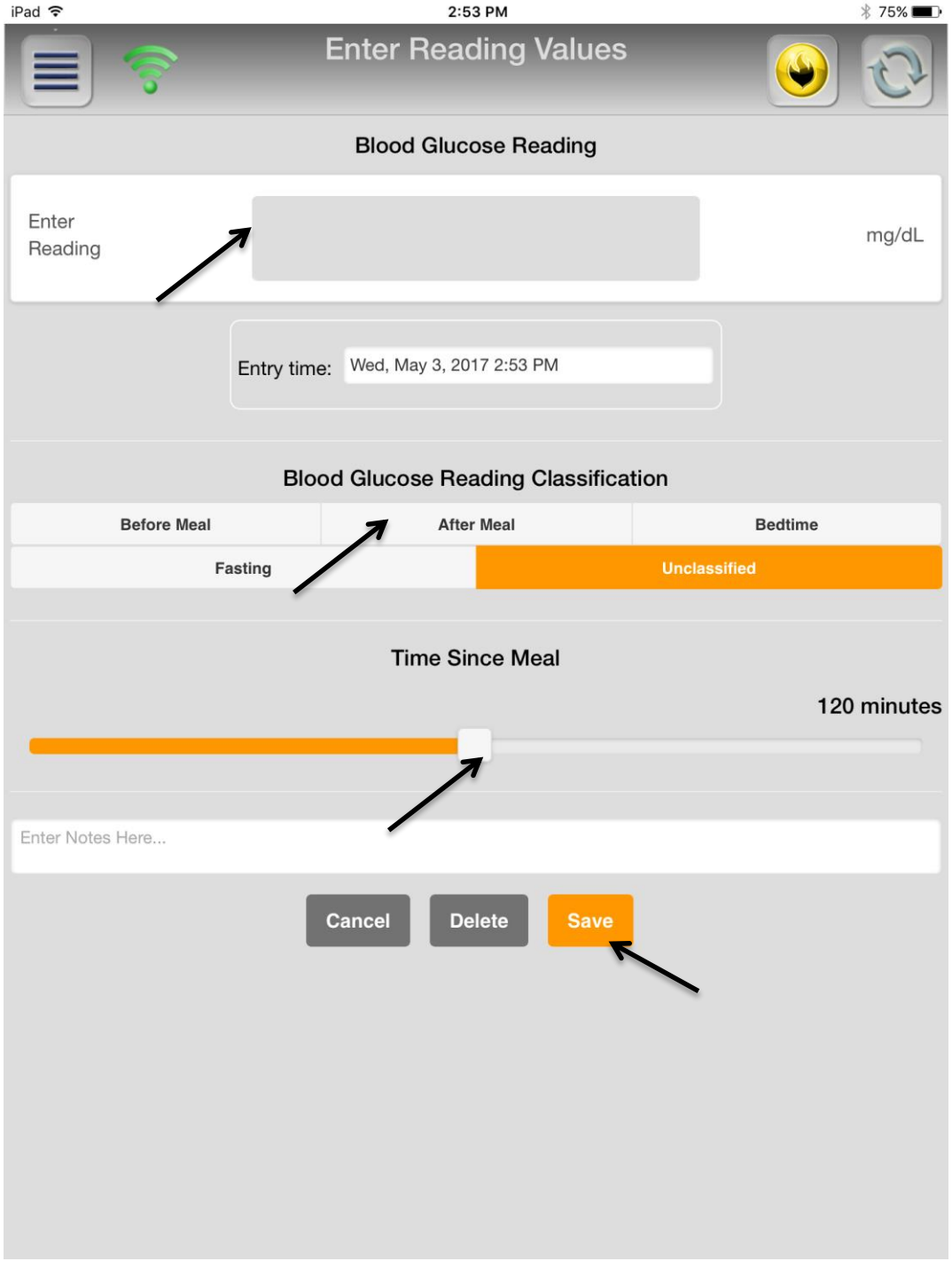
Please select a Reading Classification for your Blood Glucose reading

Enter Notes Here...

Cancel Delete Save


iPad
1:41 PM
90%
Blood Glucose
DAY
7 DAY
30 DAY
From
25-Apr-2017
To
01-May-2017
Blood Glucose
+
200
180
160
140
120
100
80
60
40
20
0
mg/dL
4/25
4/26
4/27
4/28
4/29
4/30
5/1
After Meal
Bedtime
Fasting
Unclassified
01-May-2017
9:24 AM
120 mg/dL
Bedtime
9:23 AM
180 mg/dL
After Meal
9:22 AM
70 mg/dL
Fasting
28-Apr-2017
8:58 AM
150 mg/dL
After Meal
8:58 AM
120 mg/dL
Bedtime
Summary
Glucose
BP
Activity
Weight


iPad
1:42 PM
90%
Add Reading
Add Blood Glucose Reading:
Add From My Device
Tap To Add Manually
Cancel
More
Summary
Glucose
BP
Activity
Weight


iPad
2:53 PM
75%
Enter Reading Values
Blood Glucose Reading
Enter Reading
mg/dL
Entry time:
Wed, May 3, 2017 2:53 PM
Blood Glucose Reading Classification
Before Meal
After Meal
Bedtime
Fasting
Unclassified
Time Since Meal
120 minutes
Enter Notes Here...
Cancel
Delete
Save

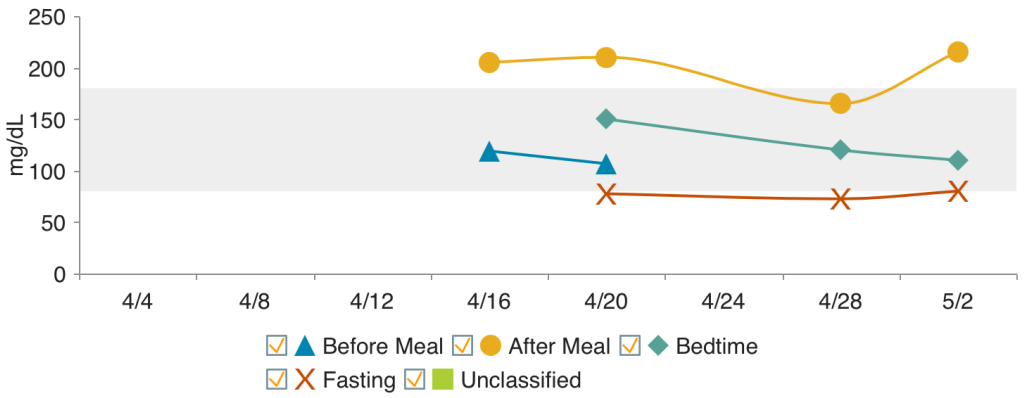
iPad 1:45 PM 89%

Blood Glucose

DAY | 7 DAY | 30 DAY

From 04-Apr-2017 To 03-May-2017

Blood Glucose



30 Day Averages (mg/dL)

Before Meal	After Meal	Bedtime	Fasting	Unclassified
110 mg/dL	196 mg/dL	130 mg/dL	76 mg/dL	0 mg/dL

Today

1:45 PM	226 mg/dL	After Meal
8:51 AM	130 mg/dL	Bedtime
8:51 AM	210 mg/dL	After Meal
8:51 AM	80 mg/dL	Fasting

More

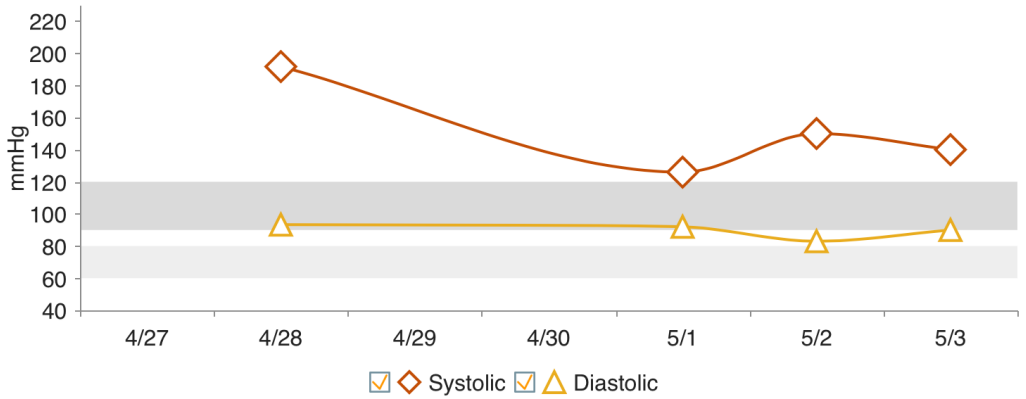
Summary | Glucose | BP | Activity | Weight

Blood Pressure

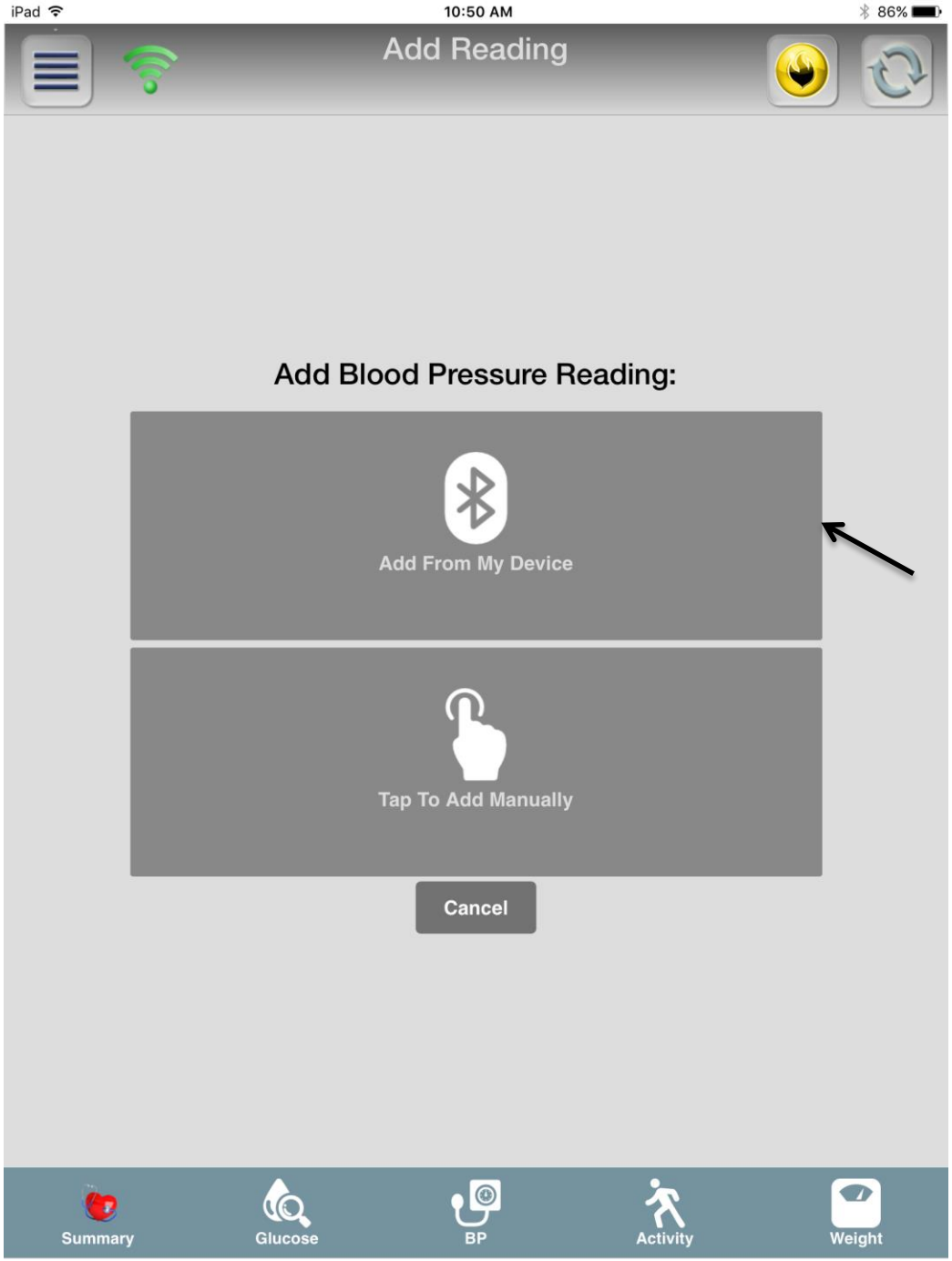
DAY | 7 DAY | 30 DAY

From 27-Apr-2017 To 03-May-2017

Blood Pressure



TODAY	SYSTOLIC/DIASTOLIC	HEART RATE
10:19 AM	140/90 mmHg	82 bpm
YESTERDAY	**SYSTOLIC/DIASTOLIC**	**HEART RATE**
1:10 PM	150/83 mmHg	76 bpm
01-MAY-2017	**SYSTOLIC/DIASTOLIC**	**HEART RATE**
9:24 AM	126/92 mmHg	70 bpm
28-APR-2017	**SYSTOLIC/DIASTOLIC**	**HEART RATE**
9:01 AM	200/110 mmHg	110 bpm


iPad
10:50 AM
86%
Add Reading
Add Blood Pressure Reading:
Add From My Device
Tap To Add Manually
Cancel
Summary
Glucose
BP
Activity
Weight

iPad 2:10 PM 85%

Add Reading

Blood Pressure Reading

1 Put on the blood pressure cuff

*Ensure cuff is 3 to 5cm above the left elbow

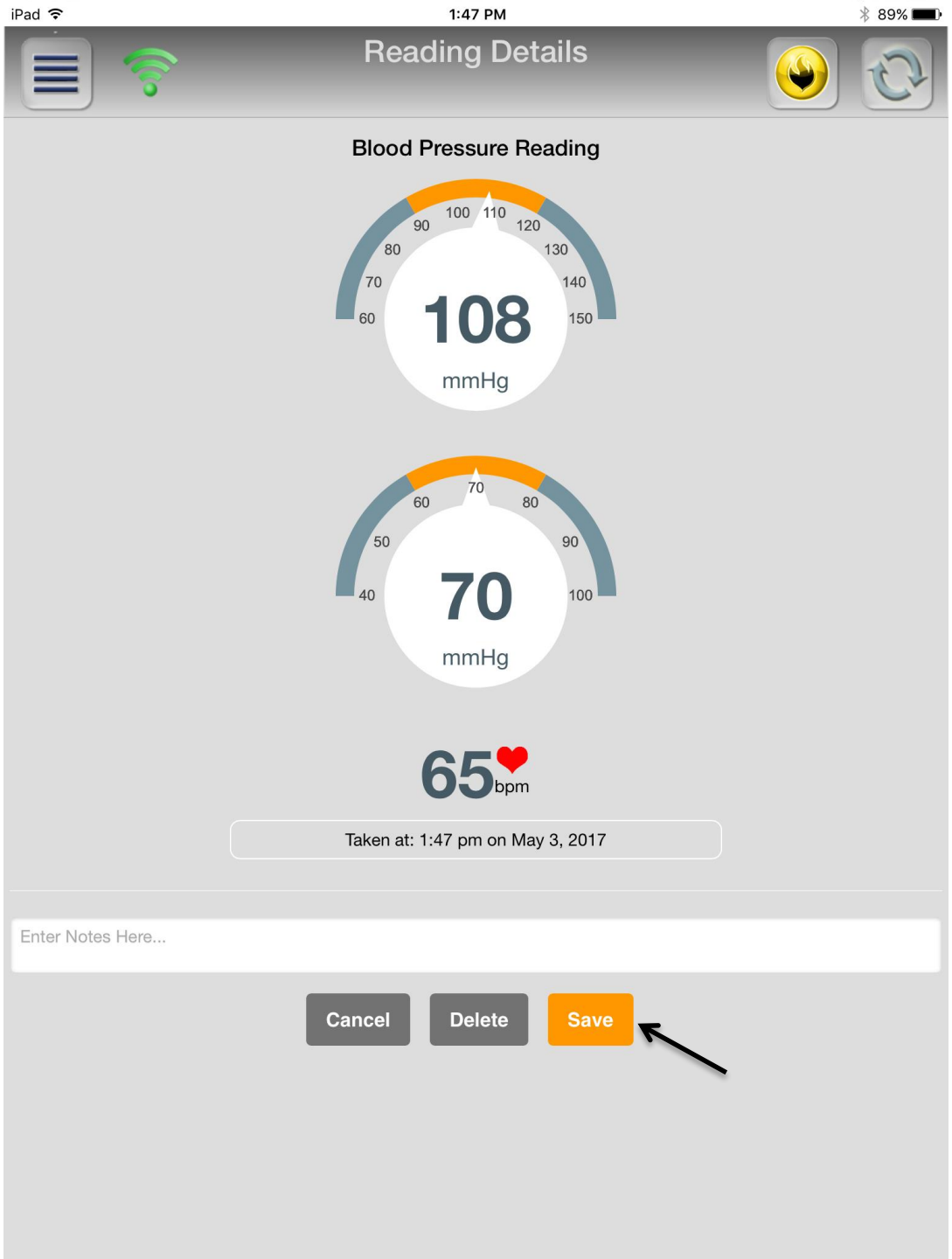
2 Connect Device

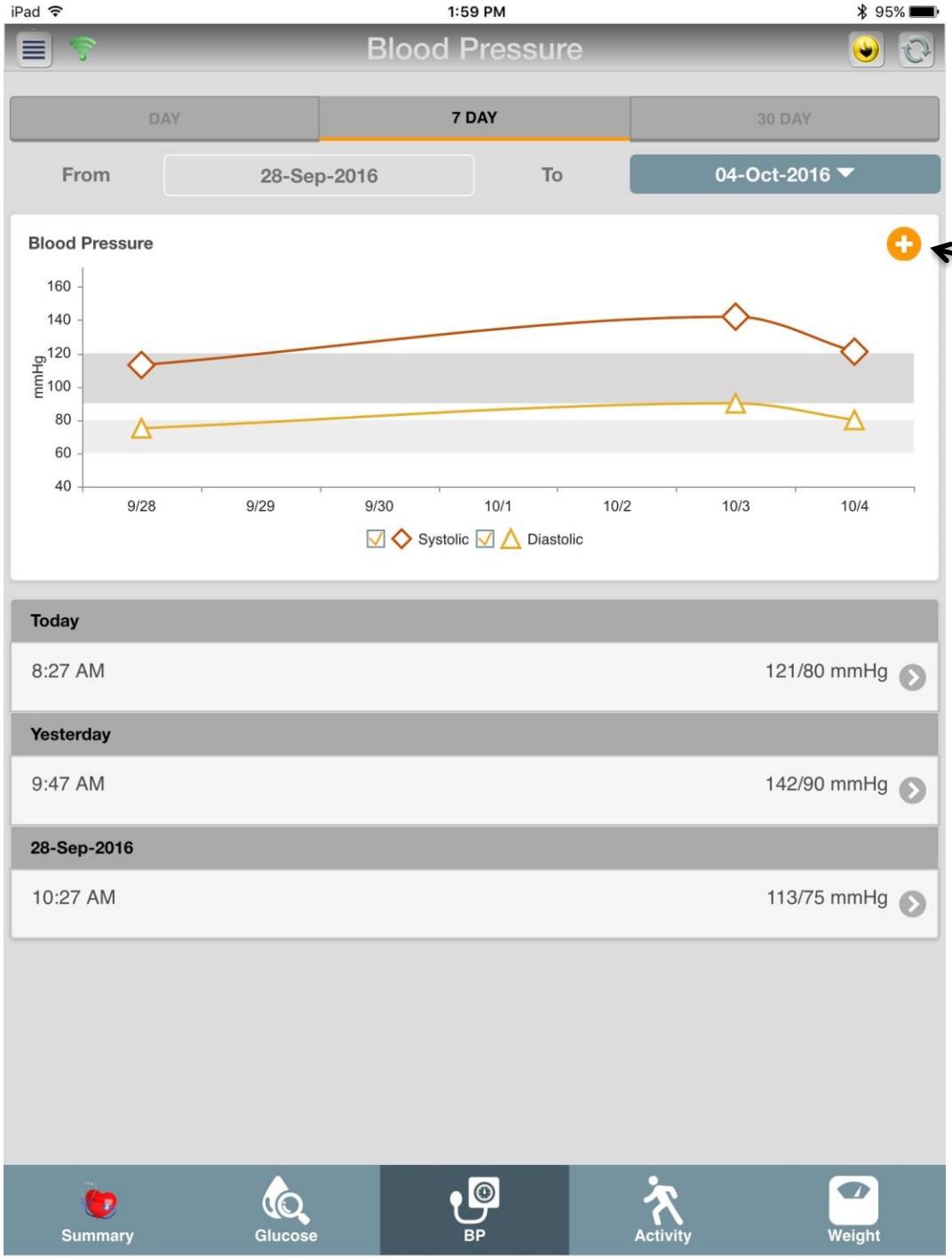
Add From My Device

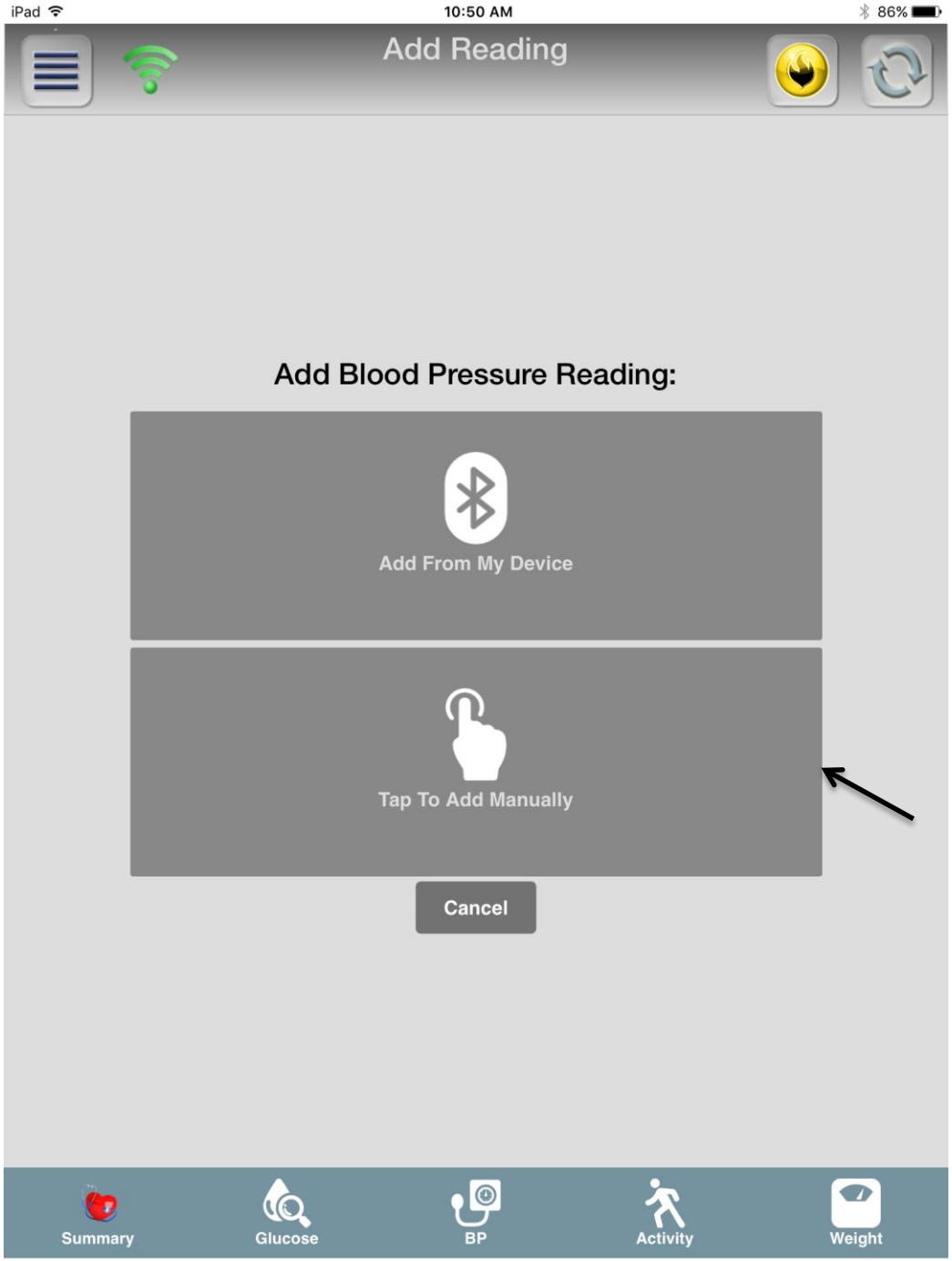
3 Press **Start** on device

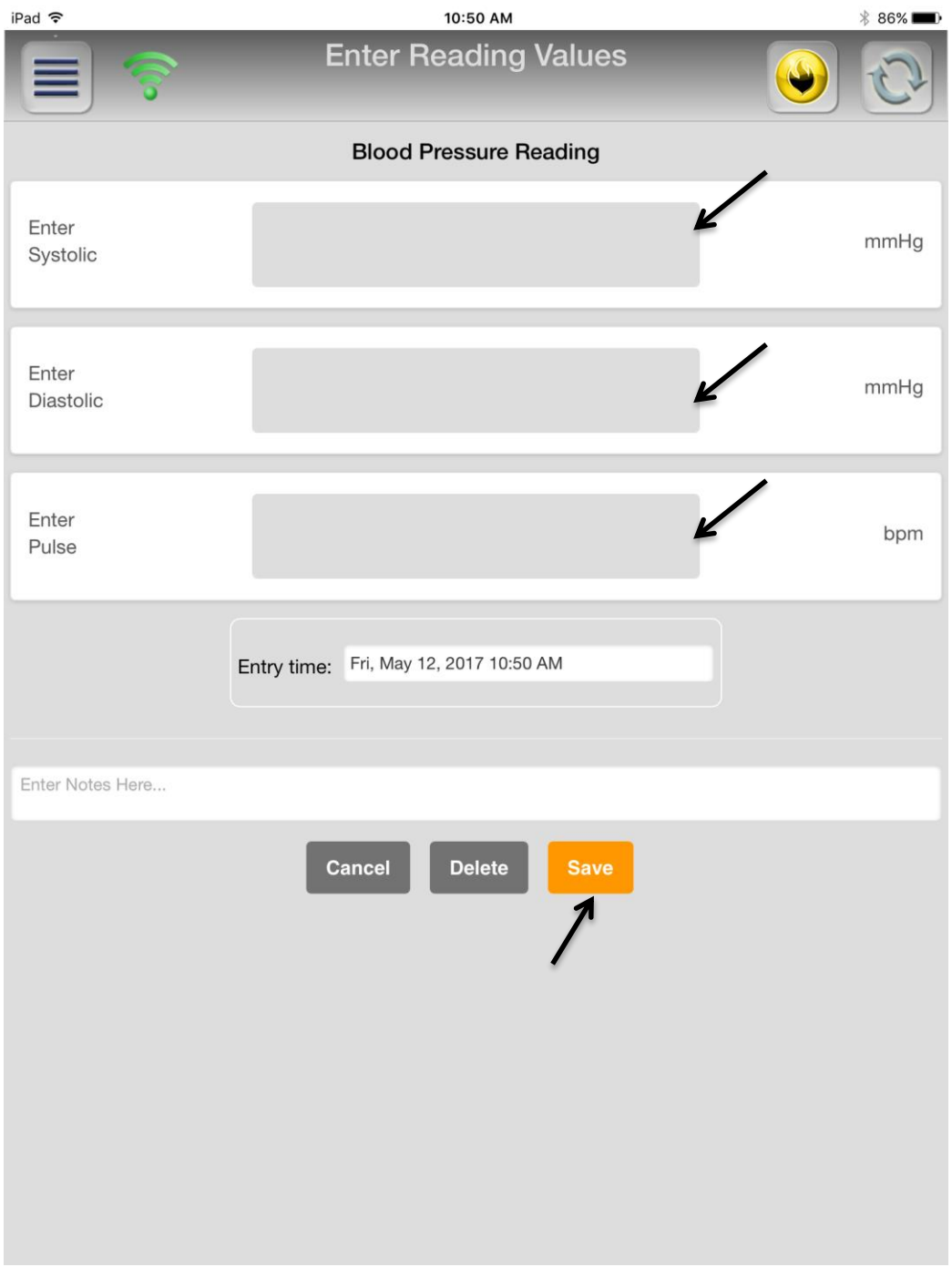
Manually Input

Cancel

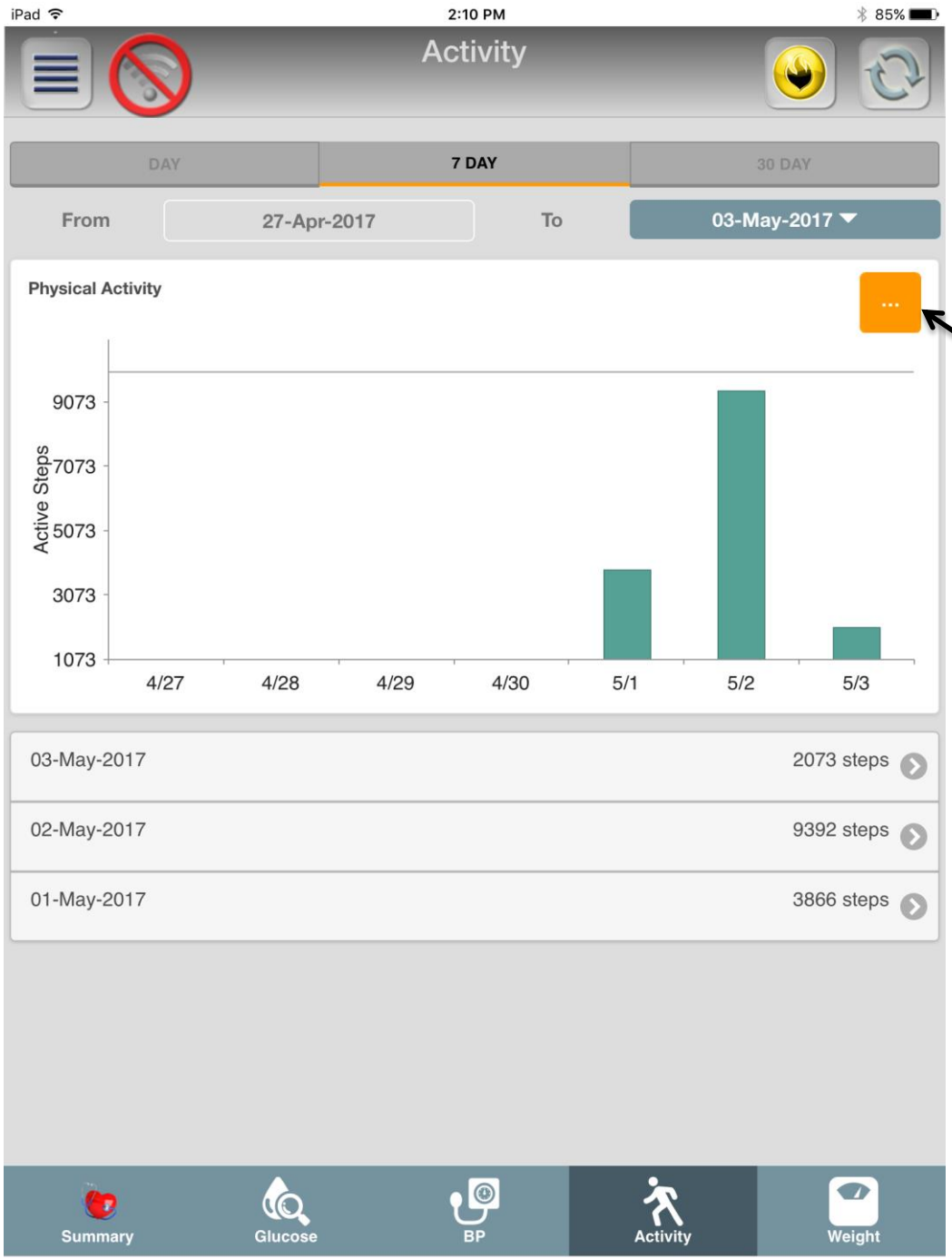

iPad
1:47 PM
89%
Reading Details
Blood Pressure Reading
60
70
80
90
100
110
120
130
140
150
108
mmHg
40
50
60
70
80
90
100
70
mmHg
65
bpm
Taken at: 1:47 pm on May 3, 2017
Enter Notes Here...
Cancel
Delete
Save

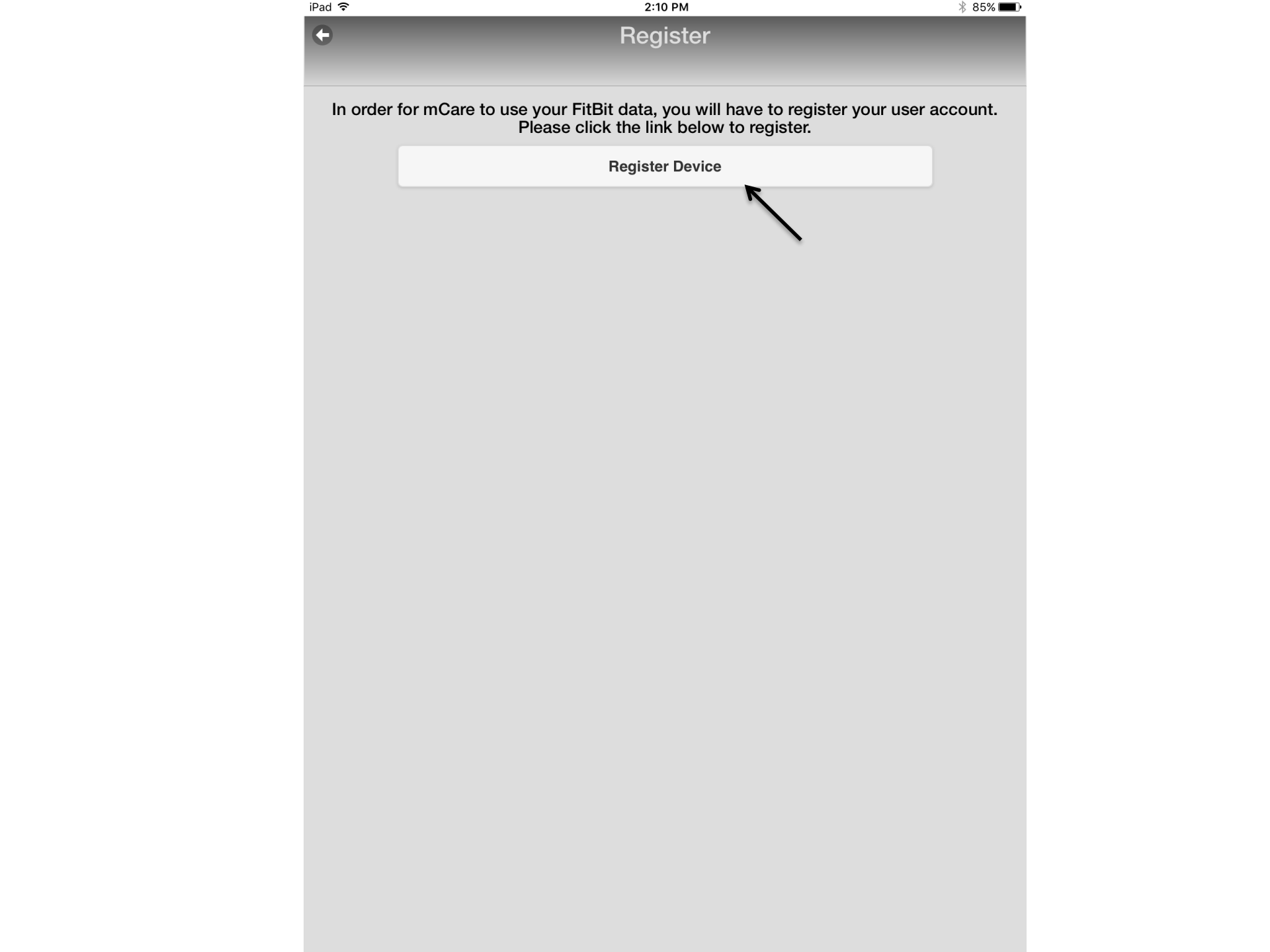

iPad
1:59 PM
95%
Blood Pressure
DAY
7 DAY
30 DAY
From
28-Sep-2016
To
04-Oct-2016
Blood Pressure
160
140
120
100
80
60
40
mmHg
9/28
9/29
9/30
10/1
10/2
10/3
10/4
Systolic
Diastolic
Today
8:27 AM
121/80 mmHg
Yesterday
9:47 AM
142/90 mmHg
28-Sep-2016
10:27 AM
113/75 mmHg
Summary
Glucose
BP
Activity
Weight

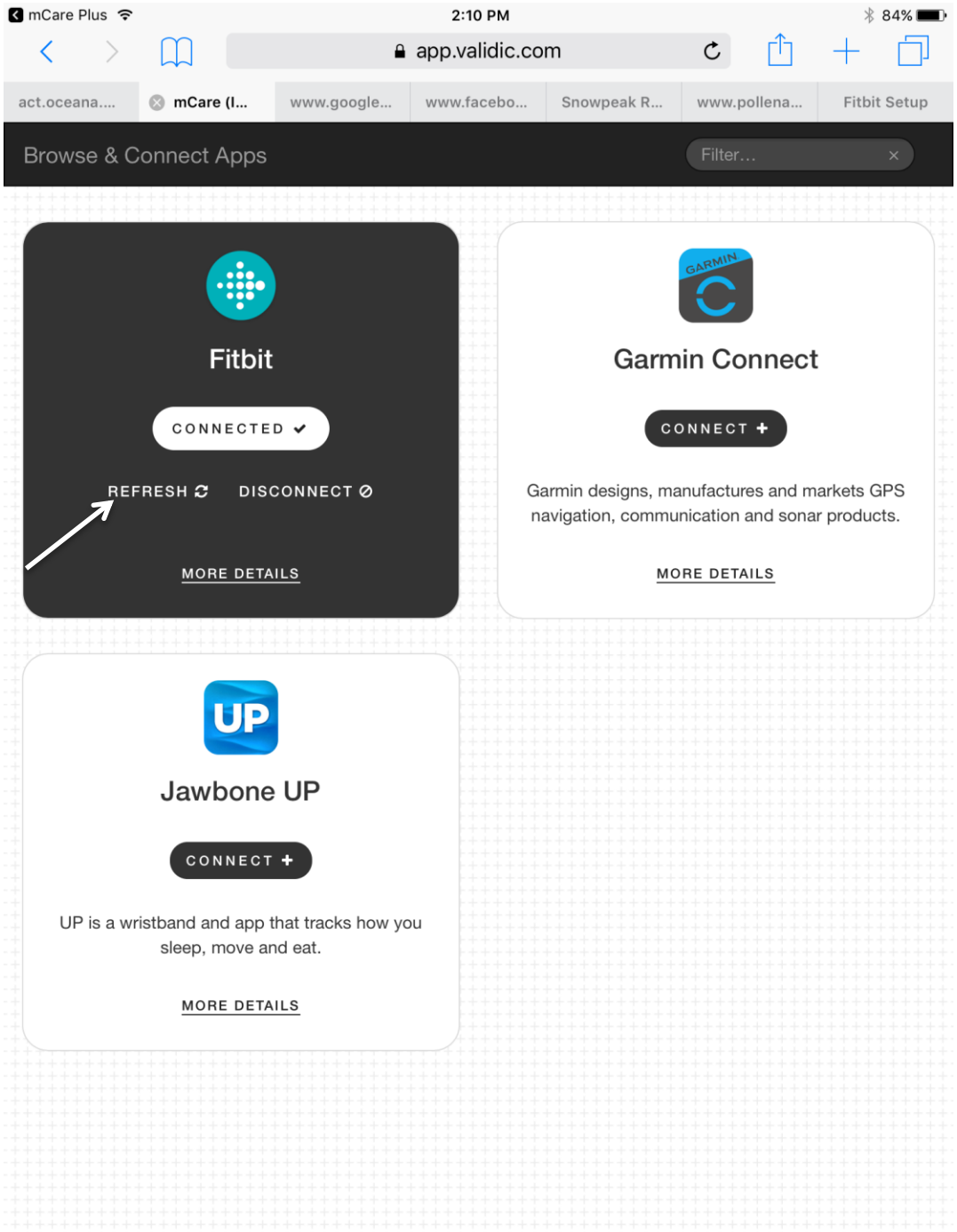

iPad
10:50 AM
86%
Add Reading
Add Blood Pressure Reading:
Add From My Device
Tap To Add Manually
Cancel
Summary
Glucose
BP
Activity
Weight

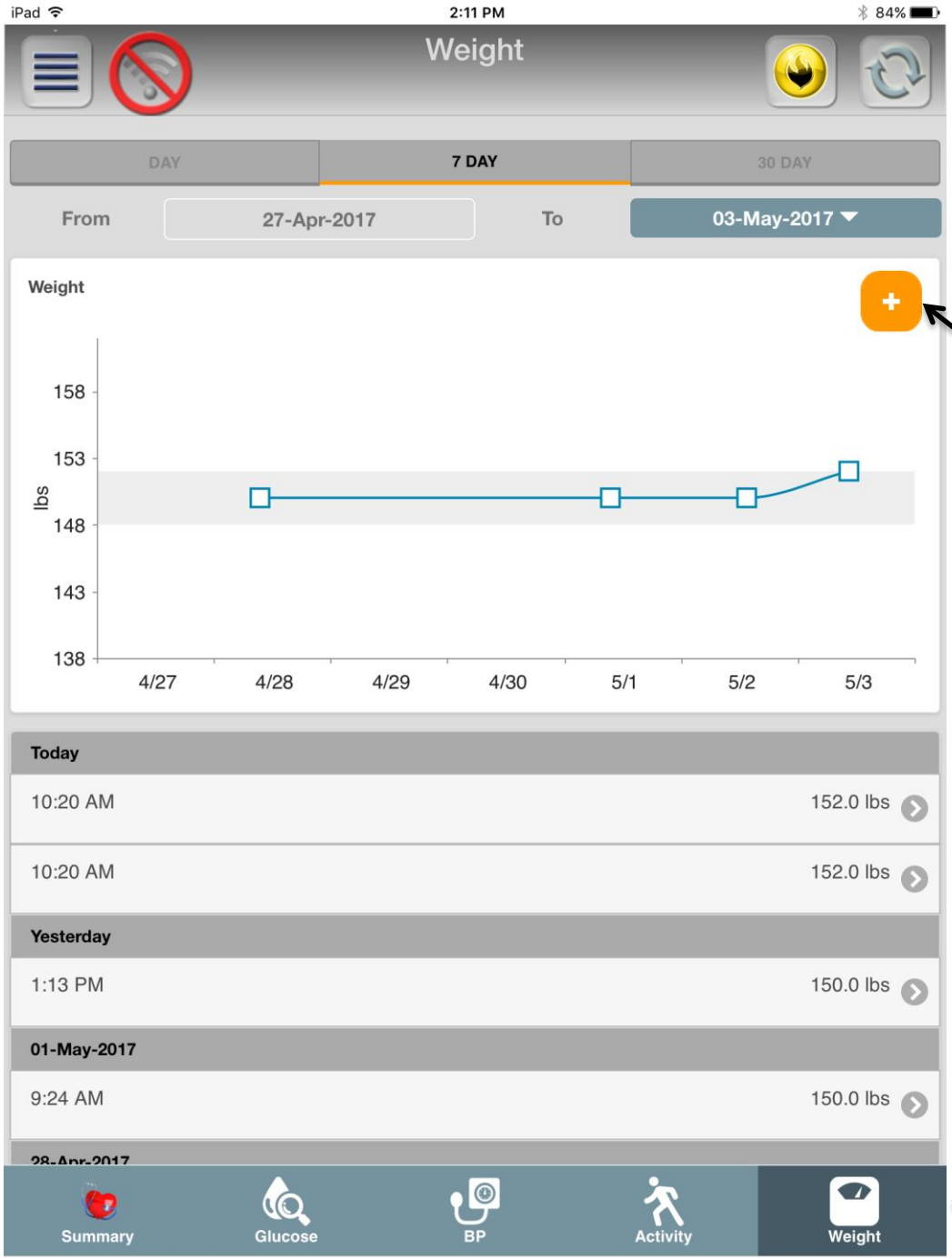

iPad
10:50 AM
86%
Enter Reading Values
Blood Pressure Reading
Enter Systolic
mmHg
Enter Diastolic
mmHg
Enter Pulse
bpm
Entry time:
Fri, May 12, 2017 10:50 AM
Enter Notes Here...
Cancel
Delete
Save

iPad
1:33 PM
91%
My Devices
Last 7 Days
Blood Glucose
250
200
150
100
50
0
mg/dL
4/27
4/28
4/29
4/30
5/1
5/2
5/3
After Meal
Bedtime
Fasting
Unclassified
Blood Pressure
220
200
180
160
140
120
100
80
60
40
mmHg
4/27
4/28
4/29
4/30
5/1
5/2
5/3
Systolic
Diastolic
Physical Activity
More
Summary
Glucose
BP
Activity
Weight

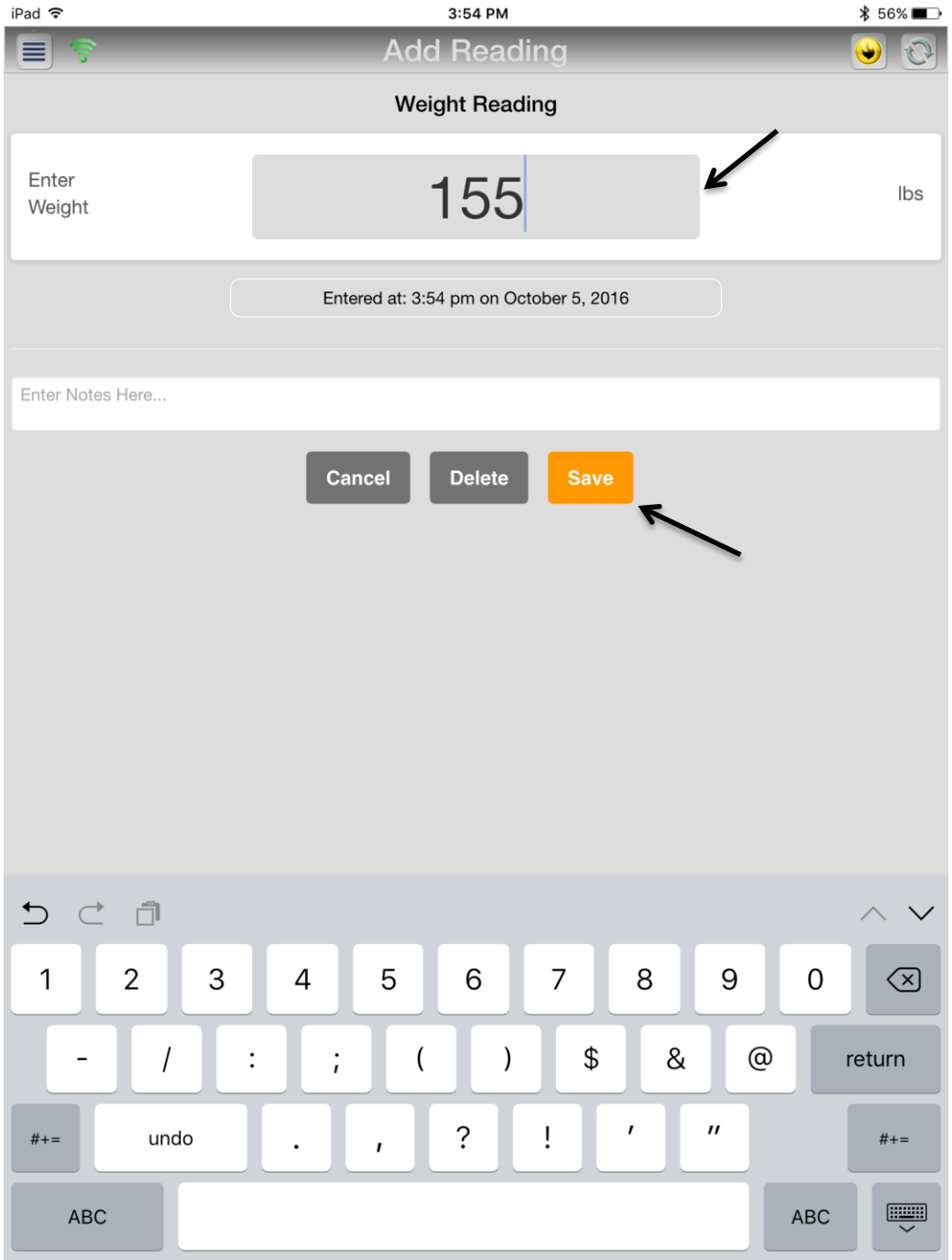

iPad
2:10 PM
85%
Activity
DAY
7 DAY
30 DAY
From
27-Apr-2017
To
03-May-2017
Physical Activity
...
Active Steps
9073
7073
5073
3073
1073
4/27
4/28
4/29
4/30
5/1
5/2
5/3
03-May-2017
2073 steps
02-May-2017
9392 steps
01-May-2017
3866 steps
Summary
Glucose
BP
Activity
Weight


iPad
2:10 PM
85%
Register
In order for mCare to use your FitBit data, you will have to register your user account.
Please click the link below to register.
Register Device


mCare Plus
2:10 PM
84%
app.validic.com
act.oceana....
mCare (I...
www.google...
www.facebo...
Snowpeak R...
www.pollena...
Fitbit Setup
Browse & Connect Apps
Filter...
Fitbit
CONNECTED
REFRESH
DISCONNECT
MORE DETAILS
Garmin Connect
CONNECT +
Garmin designs, manufactures and markets GPS navigation, communication and sonar products.
MORE DETAILS
Jawbone UP
CONNECT +
UP is a wristband and app that tracks how you sleep, move and eat.
MORE DETAILS


iPad
2:11 PM
84%
Weight
DAY
7 DAY
30 DAY
From
27-Apr-2017
To
03-May-2017
Weight
158
153
148
143
138
lbs
4/27
4/28
4/29
4/30
5/1
5/2
5/3
Today
10:20 AM
152.0 lbs
10:20 AM
152.0 lbs
Yesterday
1:13 PM
150.0 lbs
01-May-2017
9:24 AM
150.0 lbs
Summary
Glucose
BP
Activity
Weight

iPad
2:11 PM
84%
Add Reading
Add Weight Reading:
Add From My Device
Tap To Add Manually
Cancel
Summary
Glucose
BP
Activity
Weight


iPad
3:54 PM
56%
Add Reading
Weight Reading
Enter Weight
155
lbs
Entered at: 3:54 pm on October 5, 2016
Enter Notes Here...
Cancel
Delete
Save
1 2 3 4 5 6 7 8 9 0
- / : ; ( ) $ & @ return
#+= undo . , ? ! ' " #+=
ABC
ABC

iPad
2:11 PM
84%
Add Reading
Add Weight Reading:
Add From My Device
Tap To Add Manually
Cancel
Summary
Glucose
BP
Activity
Weight

iPad 3:53 PM 56%

Add Reading

Weight Reading

1 Connect Device

Add From My Device

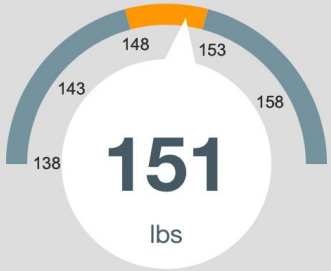
2 Stand on weight scale

Manually Input

Cancel

Reading Details

Weight Reading



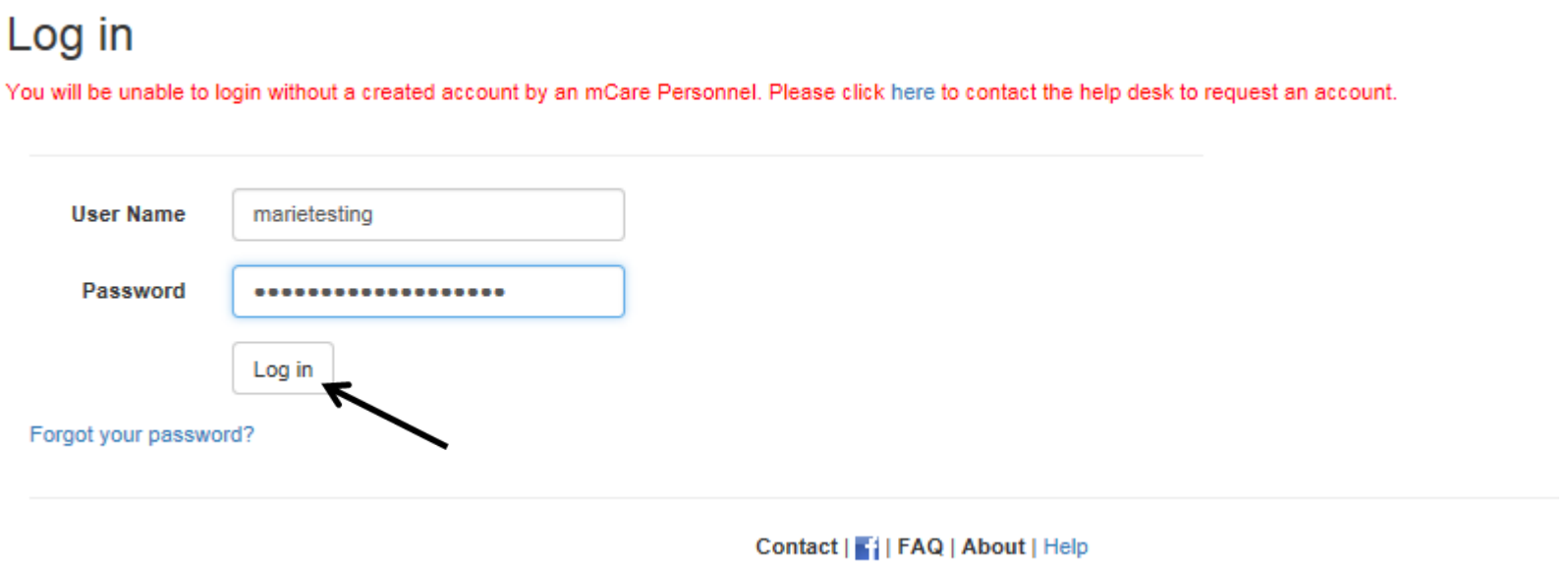
Taken at: 1:35 pm on May 15, 2017

Enter Notes Here...

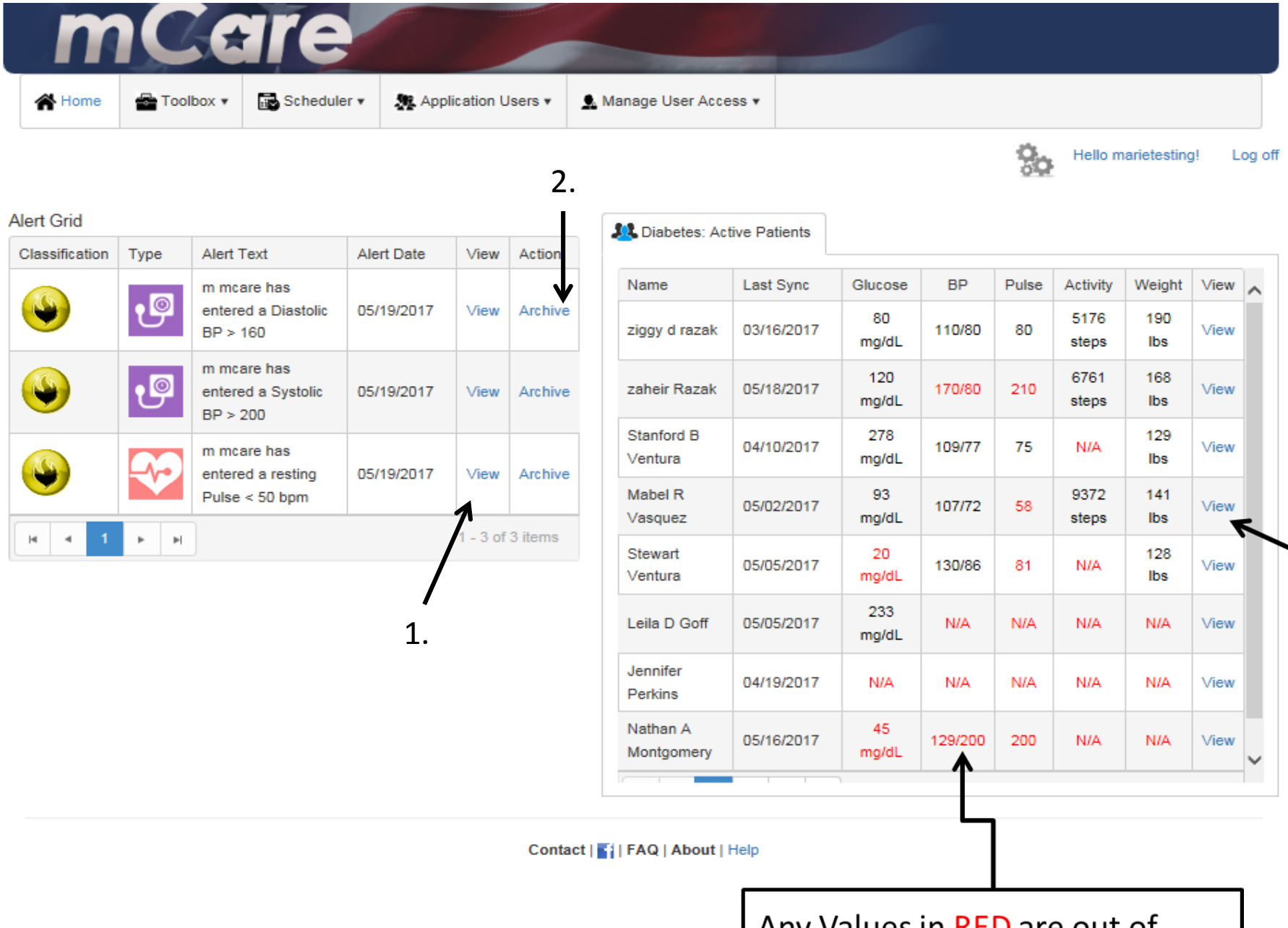
Cancel Delete Save

Provider Back-end Portal

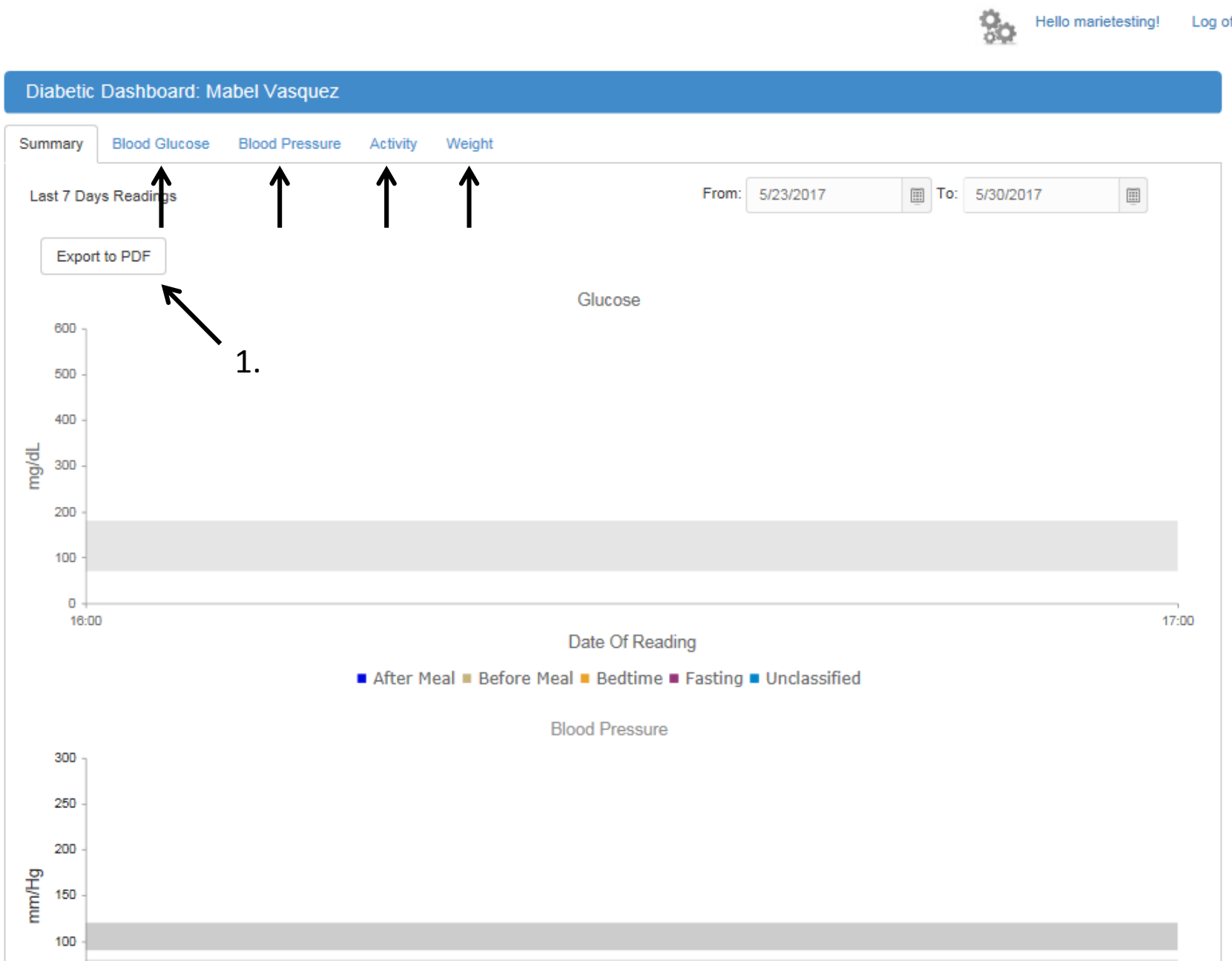
Log-In Page


Log in
You will be unable to login without a created account by an mCare Personnel. Please click here to contact the help desk to request an account.
User Name
marietesting
Password
Log in
Forgot your password?
Contact | | FAQ | About | Help

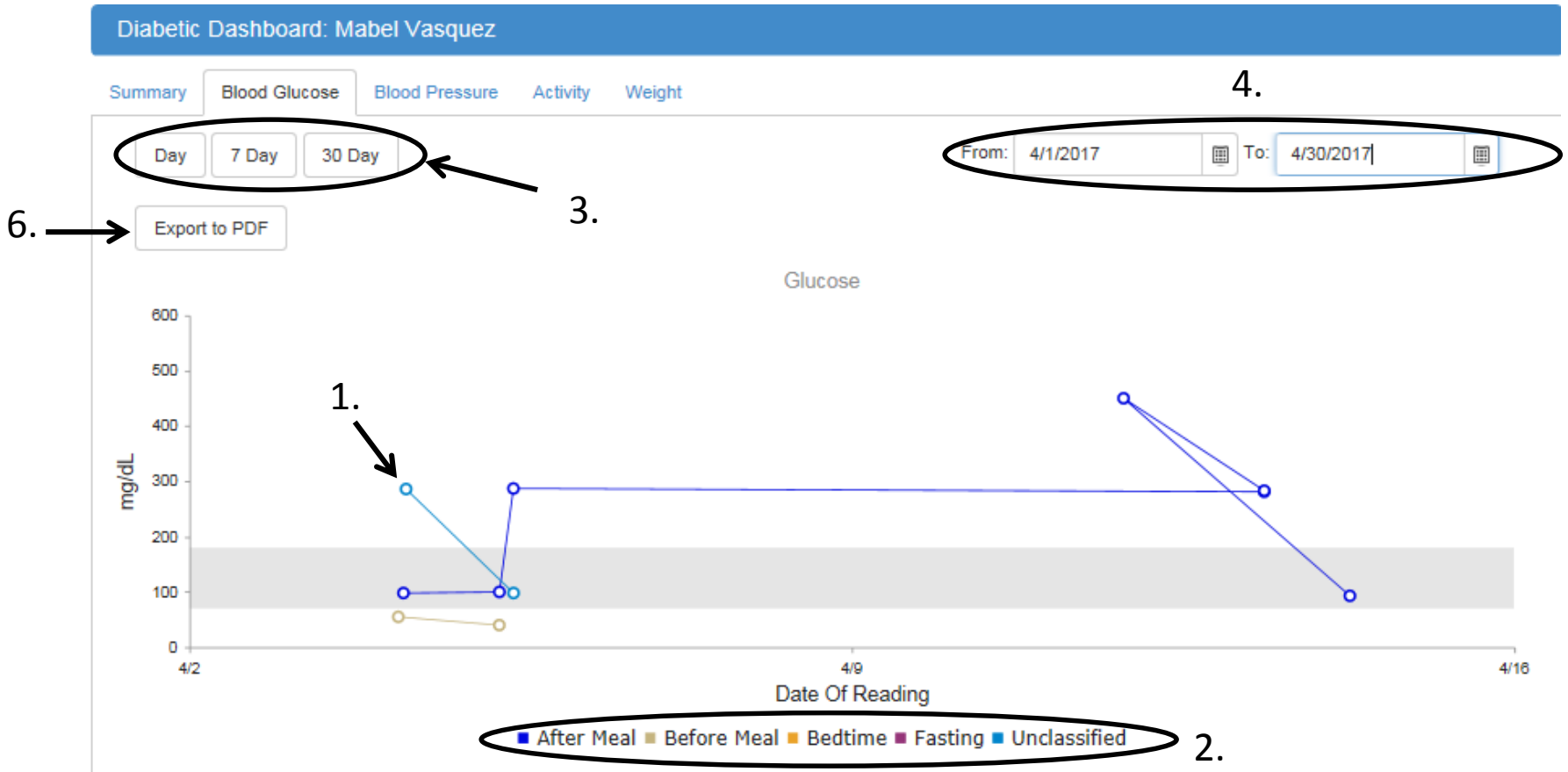
Home Page


mCare
Home
Toolbox
Scheduler
Application Users
Manage User Access
Hello marietesting!
Log off
2.
Alert Grid
Classification
Type
Alert Text
Alert Date
View
Action
m mcare has entered a Diastolic BP > 160
05/19/2017
View
Archive
m mcare has entered a Systolic BP > 200
05/19/2017
View
Archive
m mcare has entered a resting Pulse < 50 bpm
05/19/2017
View
Archive
1 - 3 of 3 items
1.
Diabetes: Active Patients
Name
Last Sync
Glucose
BP
Pulse
Activity
Weight
View
ziggy d razak
03/16/2017
80 mg/dL
110/80
80
5176 steps
190 lbs
View
zaheir Razak
05/18/2017
120 mg/dL
170/80
210
6761 steps
168 lbs
View
Stanford B Ventura
04/10/2017
278 mg/dL
109/77
75
N/A
129 lbs
View
Mabel R Vasquez
05/02/2017
93 mg/dL
107/72
58
9372 steps
141 lbs
View
Stewart Ventura
05/05/2017
20 mg/dL
130/86
81
N/A
128 lbs
View
Leila D Goff
05/05/2017
233 mg/dL
N/A
N/A
N/A
N/A
View
Jennifer Perkins
04/19/2017
N/A
N/A
N/A
N/A
N/A
View
Nathan A Montgomery
05/16/2017
45 mg/dL
129/200
200
N/A
N/A
View
Contact | | FAQ | About | Help
Any Values in RED are out of

Patient's Weekly Summary Page



Blood Glucose-Monthly Patient Readings



5.

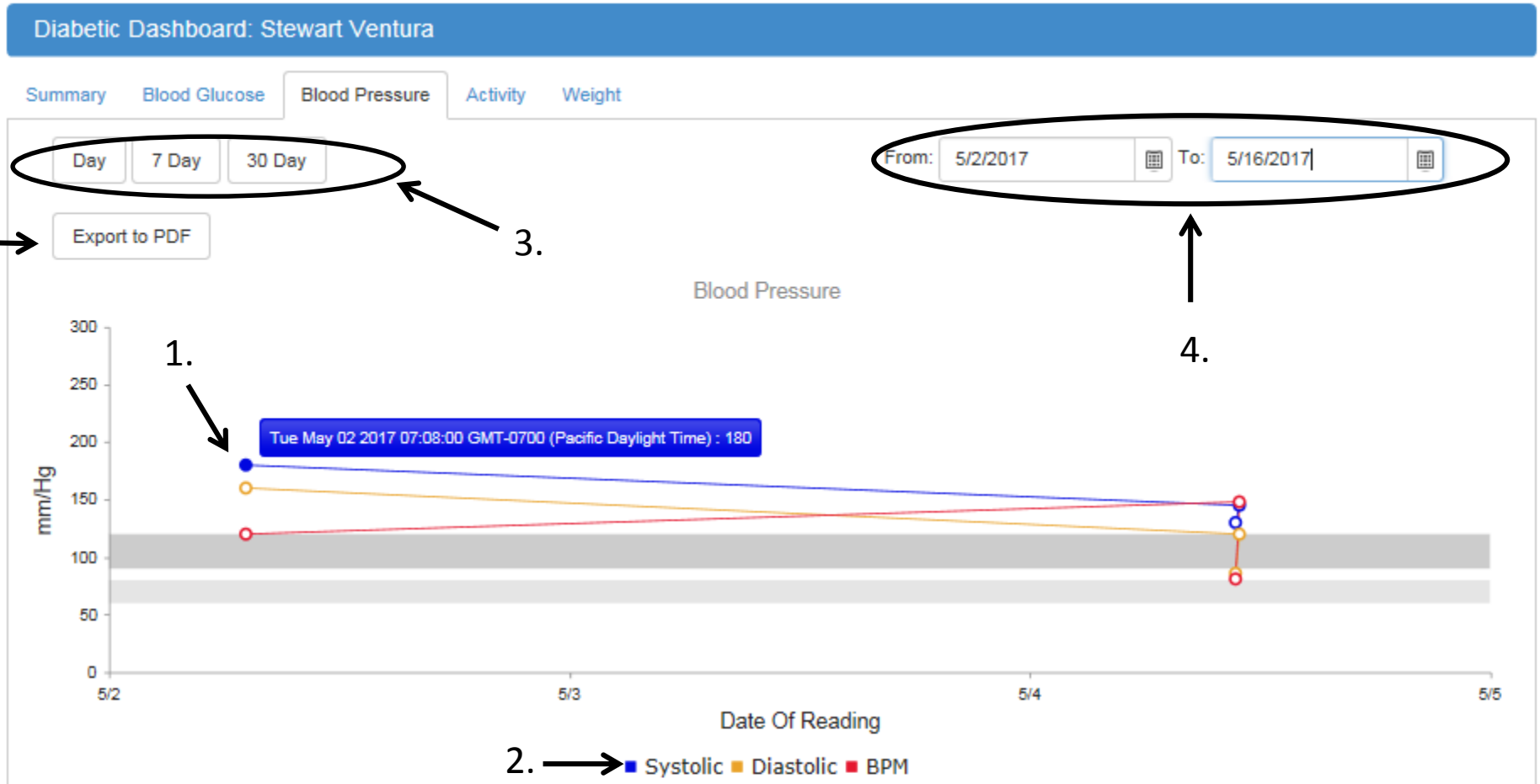
30-Day Average

Export to PDF ← 6.

Before Meal	After Meal	Bedtime	Fasting	Unclassified
0 mg/dL	0 mg/dL	0 mg/dL	0 mg/dL	0 mg/dL

Export to PDF

Blood Pressure



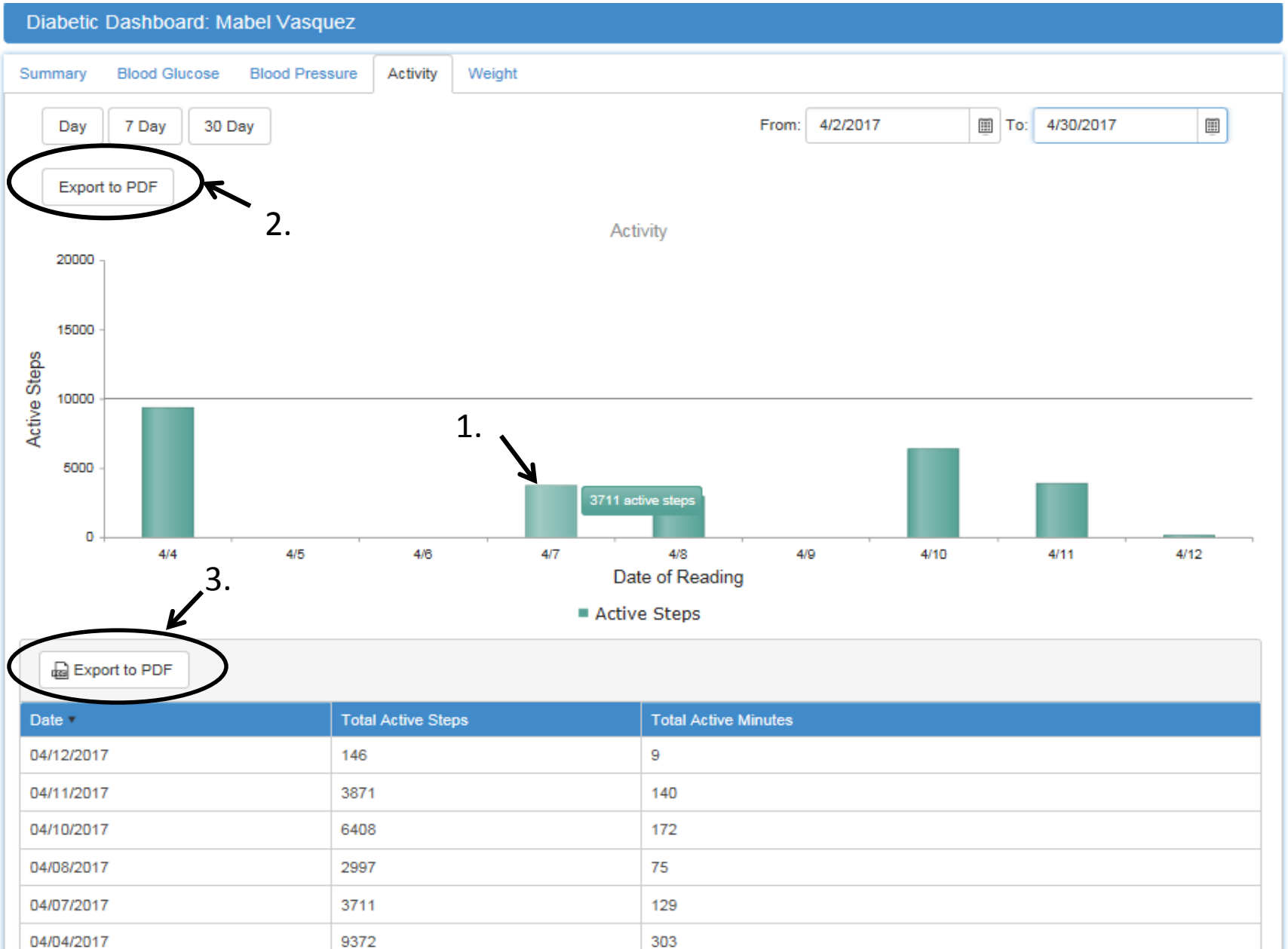
5.

Export to PDF

Date	Time	Blood Pressure Reading	Pulse	Notes
05/04/2017	10:56 AM	145 / 120 mmHg	148 bpm	
05/04/2017	10:44 AM	130 / 86 mmHg	81 bpm	
05/02/2017	7:08 AM	180 / 160 mmHg	120 bpm	

1 - 3 of 3 items

Activity-Monthly View



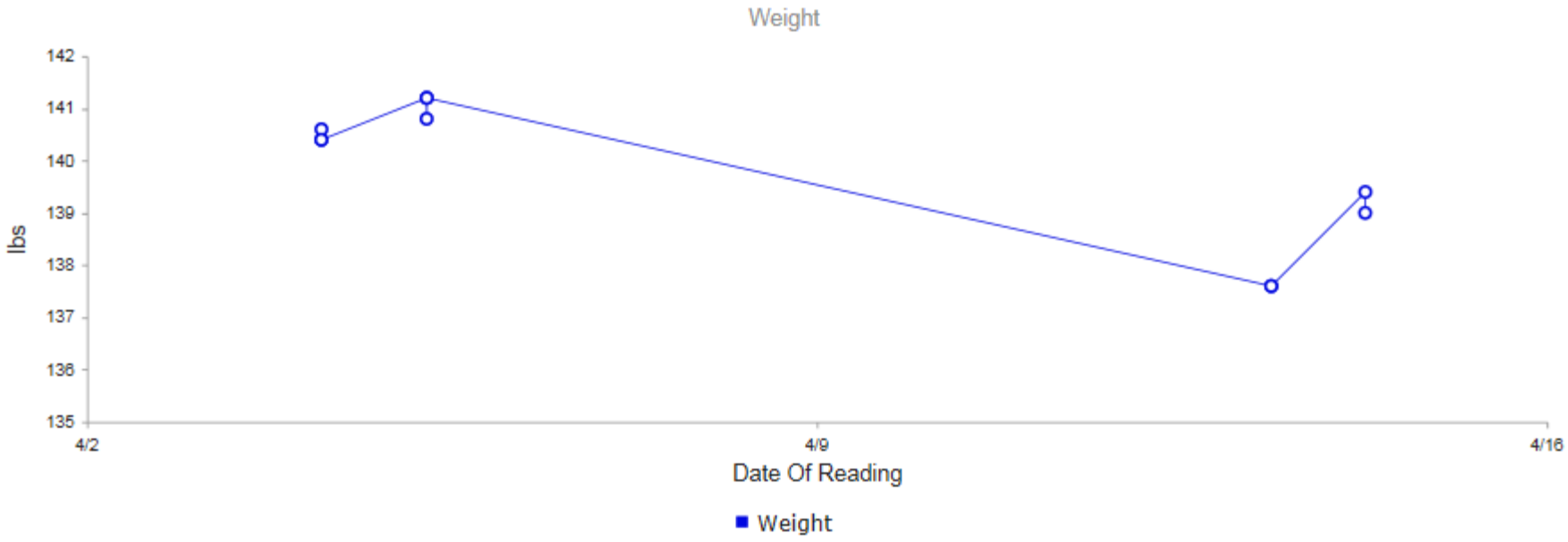
Date	Total Active Steps	Total Active Minutes
04/12/2017	146	9
04/11/2017	3871	140
04/10/2017	6408	172
04/08/2017	2997	75
04/07/2017	3711	129
04/04/2017	9372	303

Diabetic Dashboard: Mabel Vasquez

Summary | Blood Glucose | Blood Pressure | Activity | Weight

Day | 7 Day | 30 Day

From: 4/2/2017 To: 5/28/2017



Date	Time	Weight Reading	Notes
04/14/2017	6:19 AM	139.4 lbs	
04/14/2017	6:17 AM	139 lbs	
04/13/2017	8:40 AM	137.6 lbs	
04/13/2017	8:39 AM	137.6 lbs	
04/05/2017	6:13 AM	141.2 lbs	after breakfast
04/05/2017	6:12 AM	141.2 lbs	
04/05/2017	6:11 AM	140.8 lbs	
04/04/2017	5:58 AM	140.6 lbs	

1.

Enhancing mHealth Technology in the PCMH environment to Activate Chronic Care Patients

ERMS/Log Number: 14210004

Award Number: W81XWH-15C-0070

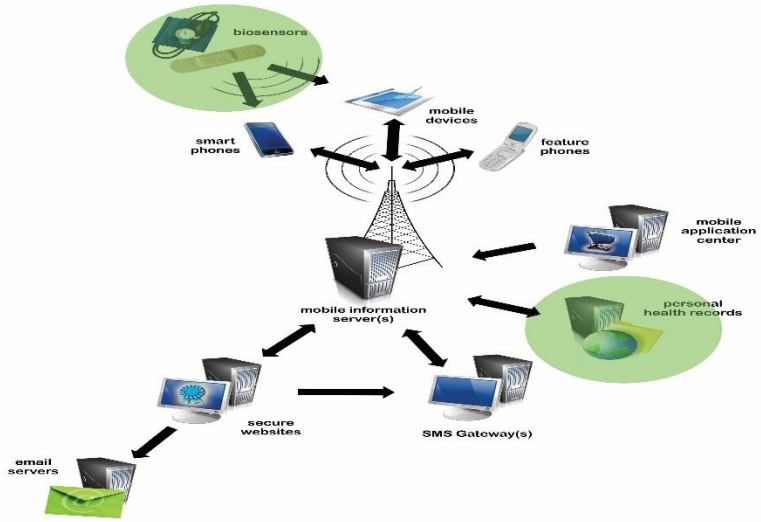
PI: Ronald W. Gimbel, PhD **Org:** Clemson University **Award Amount:** $1.22M

Study/Product Aim(s)

- Integrate mHealth technology into the clinical workflow of the PCMH model;
- Activate Type 2 diabetes patients in disease self-management behaviors through novel use of mHealth technology;
- Advance understanding of how patient complexity and degree of "sickness" may influence mHealth technology use in disease self-management; and
- Map patient-initiated biomedical data into clinical documentation and a decision support useful in chronic care management.

Approach

A multi-site phased feasibility study, conducted in the PCMH environment of Nellis AFB and Madigan AMC. Includes user-centered design research and feasibility testing followed by 12 month clinical trial. Study is partnership between TATRC (technology developers), Clemson University (researchers), and MTFs.



Timeline and Cost

Activities / CY	15	16	17	18
CRADA & IRB approvals				
User-centered design & testing				
Clinical trial at 2 MTFs				
Data analysis & reporting				
Estimated Budget ($K)	**$151**	**$480**	**$518**	**$81**

Updated: 15 MAY 2017

Goals/Milestones

CY15 Goal –*Regulatory & administrative approvals (2 months)*

- ❑ Clemson IRB and CRADA approval obtained
- ❑ Madigan IRB approval pending
- ❑ Research team training conducted; Clemson RA, Madigan AMC and Nellis AFB SRAs hired; Clinical and Developmental Advisory Teams established

CY16 Goals – *Phase I user-centered design and feasibility testing*

- ❑ User-centered design research
- ❑ Obtain Madigan IRB approval
- ❑ Feasibility testing with patients
- ❑ Modify mHealth technology incorporating lessons learned

CY17 Goals – *Phase II clinical trials at 2 MTFs*

- ❑ Randomize patients
- ❑ Formal clinical trials of enhanced mHealth technology

CY18 Goal – *Data analysis and reporting (4 months)*

- ❑ Analyze data (including time series data)
- ❑ Formal reports and manuscripts

Budget Expenditure to Date

Projected Expenditure: $1.230,749

Actual Expenditure: $747,888.40 at 7/31/17